

Product name	Quintus 5-Part Stopper	
Article No	1504373 (1 liter)	
Manufacturer	Boule Medical AB Domnarvsgatan 4 SE-163 53 Spånga, Sweden Telephone: 0046 8 744 77 00 Fax: 0046 8 744 77 20	
Country of origin	Sweden	
Product Description	Quintus Stopper is a hematology reagent used for cell counting and sizing in the Quintus Series, automated, hematology analyzers.	
Active Ingredients	Salts for isotonic stability	< 2.5 %
	Antimicrobials	< 0.1 %
	Buffering agents	< 1.0 %
Preservatives	The stopper contains anti-microbial substances to prevent contamination of bacteria or molds, these substances are biodegradable.	
Shelf life	24 months from day of manufacture. The shelf life of this product is based on accelerated and real-time stability studies. The shelf life for a new product is usually 12 months and upon confirmed real-time checks can be prolonged in 3-month intervals.	
Open bottle/container stability	3 months	
Storage	+4 °C and +35 °C. (~39-95 °F). Avoid freezing.	
Packaging and Weight	1 liter in HDPE bottle (1.1 kg), 5 liter (5.4 kg) LDPE cubitainer packed in a cardboard box.	
Package and Labels		

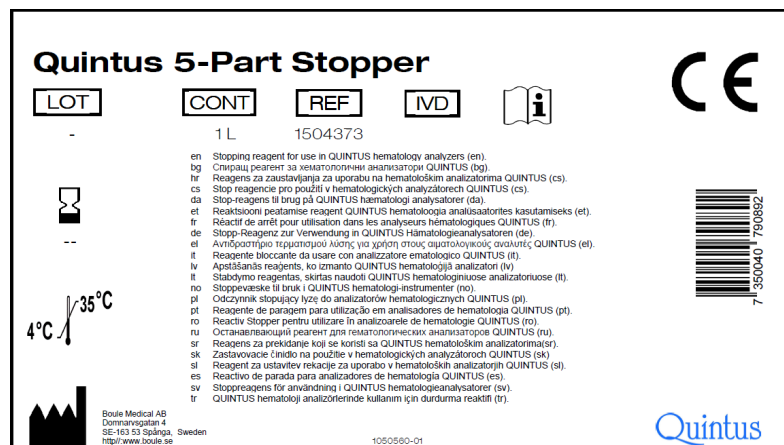


Figure 1 – Quintus 5-part Stopper, 1L package

Contains Kathon. May produce an allergic reaction.(en)/Съдържа Kathon. Може да причини алергична реакция.(bg)/Sadrží Kathon. Može izazvati alergijsku reakciju.(hr)/Obsahuje Kathon. Může vyvolat alergickou reakci.(cs)/Inneholder Kathon. Kan utløse allergisk reaktion.(da)/Sisaldab Kathon. Võib esile kutsuda allergilise reaktsiooni.(et)/Contient du Kathon. Peut produire une réaction allergique.(fr)/Enthält Kathon. Kann allergische reaktionen hervorrufen.(de)/Περιέχει Kathon. Μπορεί να προκαλέσει αλλεργική αντίδραση.(el)/Contiene Kathon. Può provocare una reazione allergica.(it)/Satur Kathon. Var izraisīt alergisku reakciju.(lv)/Sudėtyje yra Kathon. Gali sukelti alerginę reakciją.(lt)/Inneholder Kathon. Kan gi en allergisk reaksjon.(no)/Zawiera Kathon. Może powodować wystąpienie reakcji alergicznej.(pl)/Contém Kathon. Pode provocar uma reacção alérgica.(pt)/Contine Kathon. Poate provoca o reacție alergică.(ro)/Содержит Kathon. Может вызвать аллергическую реакцию.(ru)/Sadrží Kathon. Može izazvati alergijsku reakciju.(sr)/Obsahuje Kathon. Může vyvolat alergickou reakciu.(sk)/Vsebuje Kathon. Lahko povzroči alergijski odziv.(sl)/Contiene Kathon. Puede provocar una reacción alérgica.(es)/Innehåller Kathon. Kan orsaka en allergisk reaktion.(sv)/Kathon içerir. Alerjik reaksiyona neden olabilir.(tr)

EUH 208 ArtNr. 1050820 **Boule Medical AB**

Figure 2 – Additional CLP information



Quintus 5-Part Stopper

LOT CONT REF IVD

1L 1504373

4°C / 35°C

en Stopping reagent for use in QUINTUS hematology analyzers (en).
 bg Стрпачи реагент за използване в анализатори QUINTUS (bg).
 hr Reagens za zaustavljanje za uporabu na hematološkim analizatorima QUINTUS (cs).
 cs Stop reagentie pro použití v hematologických analyzátoch QUINTUS (cs).
 da Stop-reagens til brug på QUINTUS hematologi analyzatorer (da).
 et Reaktiiv loetakse reagent QUINTUS hematoloogia analüsaatorites kasutamiseks (et).
 fr Réactif de arrêt pour utilisation dans les analyseurs hématologiques QUINTUS (fr).
 de Stopp-Reagens zur Verwendung in QUINTUS Hämatologieanalyzatoren (de).
 el Αντδραστηριο τρεπτομοιο λδση για χρηση στους αιματολογικοσ αναλυτεσ QUINTUS (el).
 it Reagente bloccante da usare con analizzatore ematologico QUINTUS (it).
 lv Apsildzins reagentis, ko izmanto QUINTUS hematoloģijā analizatorā (lv).
 no Stoppvæske til bruk i QUINTUS hematologi-instrumenter (no).
 pl Odczynnik stopniący tyże do analizatorów hematologicznych QUINTUS (pl).
 pt Reagente de paragem para utilização em analisadores de hematologia QUINTUS (pt).
 ro Reactiv Stopper pentru utilizare în analizoarele de hematologie QUINTUS (ro).
 ru Остановительный реагент для гематологических анализаторов QUINTUS (ru).
 sr Reagens za prekidanje koji se koristi sa QUINTUS hematološkim analizatorima (sr).
 sk Zastavovacie číadlo na použitie v hematologických analyzátoch QUINTUS (sk).
 sl Reagent za ustavitve reakcije za uporabo v hematoloških analizatorjih QUINTUS (sl).
 es Reactivo de parada para analizadores de hematología QUINTUS (es).
 sv Stoppreagens för användning i QUINTUS hematologianalysatorer (sv).
 tr QUINTUS hematoloji analizörlerinde kullanılan için durdurma reaktifi (tr).

Boule Medical AB
Domnarvsgatan 4
SE-163 53 Spånga, Sweden
http://www.boule.se

1050560-01

Quintus

Figure 3 – Label on bottle

Recycling information

Part	Material	Weight (g)
Box	Cardboard	220
Politainer including cap	Plastic	100
Bottle 1L	Plastic	67

Warning and Precautions

Not classified as hazardous according to CLP (EC regulation 1272/2008), information given on added label. Use good laboratory practice. Avoid contact with skin, eyes, and clothing. Do not swallow.

Instructions for use

Use in accordance with manufacturer's instructions for use and follow Operator manual for connection and fill instruction.

Quality Control Specifications

Test	Specifications
pH	10.8 - 11.2
Osmolality (mOsm/kg)	830 - 860
Conductivity (mS/cm)	42.7 – 43.3
Particles (WBC channel)	≤ 0.1
Appearance	Clear, colorless liquid

*Performance test using calibrated blood cell counter at Boule Medical reference laboratory. All parameters except mid cells are tested. Accepted reference 95% to 105% of expected control blood sample values.

Product Conformity

Directives	Standards/Comments
98/79/EEC In Vitro Diagnostic Medical Device Directive (IVD)	Using Annex III as the conformity assessment procedure

Precision Testing (Instrument)

Parameter	RBC	MCV	HGB	PLT	WBC
CV	≤ 1.5 %	≤ 1.0 %	≤ 1.5 %	≤ 5 %	≤ 3.0 %

Scatter diagrams

Quintus displays the results of the optical measurements in a scatter diagram representation.

- Scatter diagrams represent data in a two-dimensional plane.
- There are two scatter diagrams in the patient report: the 4-DIFF and the BASO
-

Population (4-diff diagram)	Color on scatter diagram
Artifact	BLACK
Lymphocytes	BLUE
Monocytes	GREEN
Neutrophil granulocytes	MAGENTA
Eosinophil granulocytes	ORANGE

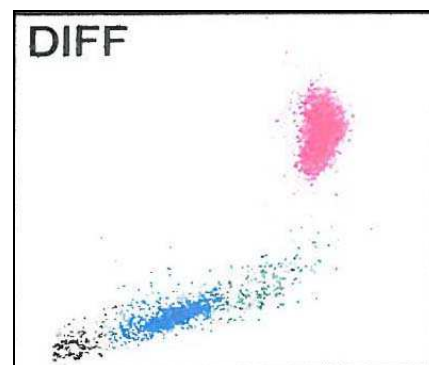


Figure 4 – 4-diff diagram

Population (Basophil diagram)	Color on scatter diagram
WBC without Basophil	BLUE
Basophil granulocytes	MAGENTA

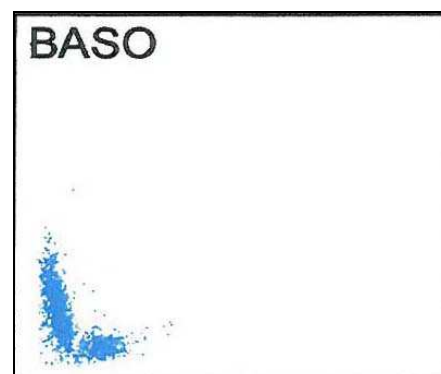


Figure 5 – Basophil diagram



Histograms

Impedance based measurements are represented on histograms. These diagrams show the number of cells against cell size.

- There are two histograms: RBC and PLT.
- Discriminators (thresholds) are displayed with red color.
- The PLT histogram is the magnified section of the left-hand side of the RBC curve.

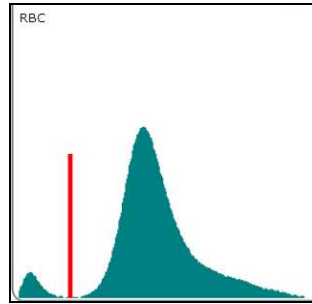


Figure 6 – RBC histogram

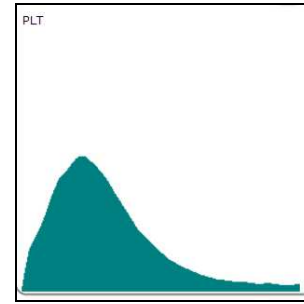


Figure 7 – PLT histogram

Manufacturing Process

For the manufacturing process and the specific process control points for this reagent see the flowchart below. The process starts with raw materials for the manufacturing of the reagent being checked in by the content of certificates (e.g. Batch Specific Certificate of Analysis) against acceptance limits and by follow-up analysis of at least one specific characteristic chemical property (e.g. pH in solution). The process is completed with final QC parameter, functional, and bacterial testing, the release by QA accompanied by the Certificate of Analysis, and the approved reagent moved to stock.

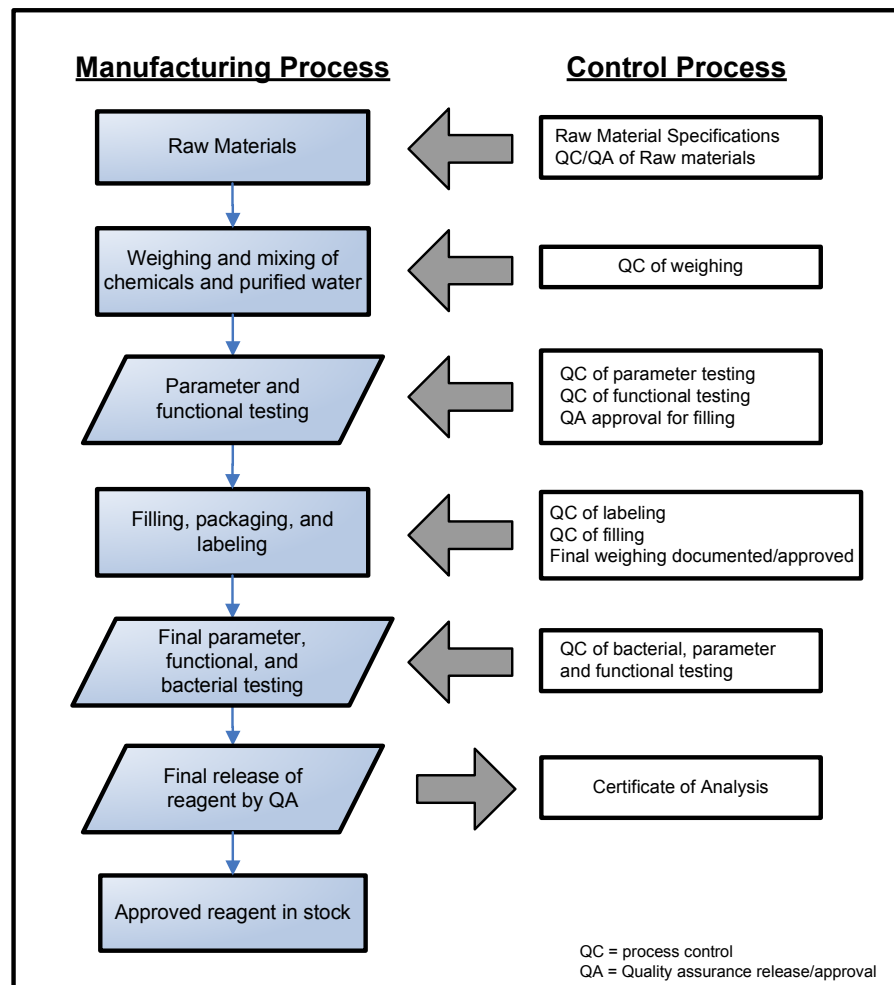


Figure 8 Flow chart for manufacturing and quality control

INTENDED USE

Boule Cal-5Diff G2 Hematology Calibrator is manufactured for calibration of multi-parameter hematology analyzers.



SUMMARY AND PRINCIPLES

Multi-parameter hematology analyzers require regular calibration in order to produce accurate results on patient samples. Calibration can be accomplished by transferring information to the analyzer through fresh blood samples, which have been assayed by reference methods. A more direct and convenient approach is to use a calibrator material with System Specific Values (SSV) assigned such as Boule Cal-5Diff G2.

Boule Cal-5Diff G2 is a stable suspension of red blood cells, white blood cells and platelets. Assigned values are derived from replicate analyses on whole blood calibrated hematology analyzers (see reference procedures). A user analyzes Boule Cal-5Diff G2 on their instrument and computes calibration factors by comparing recovered values and assigned values. These factors provide the basis for making adjustments to the instrument.

REAGENTS

Boule Cal-5Diff G2 contains treated, stabilized human erythrocytes and a stabilized platelet-sized component in an isotonic, bacteriostatic medium. Fixed erythrocytes are added to simulate leukocytes.

STORAGE AND STABILITY

Boule Cal-5Diff G2 is shipped in a thermally insulated container designed to keep it cool. When stored at 2-10°C, sealed vials are stable at least until the expiration date shown on the TABLE OF EXPECTED RESULTS. Open Vial stability is 5 days after opening when returned to refrigerator after each use. Storage of product with cap down (inverted) might require additional mixing for complete resuspension of cellular components.

INDICATION OF INSTABILITY OR DETERIORATION

Inability to obtain expected values may indicate product deterioration. Discoloration of the product may be caused by overheating or freezing during shipping or storage. Darkly colored supernatant may be indicative of product deterioration; however, moderately colored supernatant is normal and should not be confused with product deterioration. If the recovered values are not within the expected ranges:

1. Review the calibrator product package insert and the operating procedure of the instrument.
2. Check the expiration date of the Boule Cal-5Diff G2. Discard outdated products.
3. Test an additional unopened vial of Boule Cal-5Diff G2.

INSTRUCTIONS FOR USE

1. Remove Boule Cal-5Diff G2 Calibrator from refrigeration and allow to warm at ambient temperature (18-32°C) for 10-15 minutes before mixing.
2. After warming, mix by hand as follows:
 - a. Roll the tube or vial slowly between the palms eight times in an upright position.
 - b. Invert the tube and slowly roll it between the palms eight times.
 - c. Continue to mix in this manner until all cells are completely suspended. Tubes stored for a long time may require extra mixing.
 - d. Gently invert the tube 8 times immediately before sampling.
 - e. Note: Use of a Mechanical Mixer is not recommended.
3. Refer to the User's manual for calibration procedure.
4. After open sampling, carefully wipe the rim of the tube and inside of the cap with a lint-free tissue. Replace the cap ensuring it is on tight.
5. Return the tubes to the refrigerator within 30 minutes of use.
6. For further assistance, please contact your local distributor.

PRECAUTIONS

- For In-Vitro diagnostic use.
- All human source material used to manufacture this product was non-reactive for antigens to Hepatitis B and negative by tests for antibodies to HIV (HIV-1, HIV-2) and Hepatitis C using techniques specified by the U.S. Food and Drug Administration. **Because no known test method can assure complete absence of human pathogens, this product should be handled with appropriate precautions.**
- This product should not be disposed in general waste, but should be disposed with infectious medical waste. Disposal by incineration is recommended.
- This product is intended for use as supplied. Adulteration by dilution or addition of any materials to the product as supplied invalidates any diagnostic use of the product.

REFERENCE PROCEDURES

WBC- A series of 1:500 dilutions are made using class A glassware. The lytic reagent is placed in the initial dilution flask before diluting to volume. The diluting agent is an isotonic solution for Beckman Coulter® instruments. The samples are counted on a Beckman Coulter Counter Z instrument.

RBC- A series of 1:50,000 dilutions are made using class A glassware. The diluting agent is an isotonic solution for Beckman Coulter® series instruments. The samples are counted on a Beckman Coulter Counter Z instrument.

Hgb- Hemoglobin concentration is determined by converting hemoglobin to hemiglobincyanide (HiCN) and measuring absorbance at 540 nm according to NCCLS H15-A2 and ICSH recommendations. Hemoglobin concentration is calculated using millimolar absorption coefficient of 11.0.

HCT- Microhematocrit values are done in replicate on each sample, with capillary tubes filled and centrifuged according to the NCCLS H7-A2 document. K3EDTA is used as the anticoagulant for collection of fresh specimens. The packed cell volume, or hematocrit, is read directly using a precision metric scale. No correction is made for trapped plasma.

Plt- A series of 1:125 macrodilutions are prepared using class A glassware in 1% Ammonium Oxalate. Charged hemacytometers are allowed to stand 20-30 minutes. Cells are counted using phase-contrast microscopy technique.

MPV- Based on a method using latex particles.

ORDERING INFORMATION AND SERVICE

Contact your local distributor for orders and support. Please have the catalog number ready for orders. For other assistance contact Boule Medical AB at phone +46 8 7447700, fax +46 8 7447720 or info@boule.se.

For translation of this instruction and explanation to symbols see www.quintusSpart.com/support/downloads

Ordering no:	Description	Packaging
1504375	Boule Cal-5Diff G2	1 x 3 mL
1504376	Boule Con-5Diff G2Tri	6 x 3 mL
1504382	Boule Con-5Diff G2 Low	1 x 3 mL
1504379	Boule Con-5Diff G2 Low	6 x 3 mL
1504381	Boule Con-5Diff G2 Norm	1 x 3 mL
1504378	Boule Con-5Diff G2 Norm	6 x 3 mL
1504380	Boule Con-5Diff G2 High	1 x 3 mL
1504377	Boule Con-5Diff G2 High	6 x 3 mL

INTENDED USE

For *in vitro* diagnostic use as a control to monitor the performance of multi-parameter hematology instruments.



SUMMARY AND PRINCIPLES

Boule Con-5Diff G2 Hematology Control is prepared from stabilized human blood so that repeated measurements can be made daily to monitor the performance of hematology analyzer systems. ASSIGNED VALUES and EXPECTED RANGES are determined on systems using specific Boule reagents. ASSIGNED VALUES are confirmed by multiple analysis of the control product and should be considered a **suggested average** until you establish your own running mean.

REAGENTS

Boule Con-5Diff G2 Hematology Control contains treated, stabilized human erythrocytes and a stabilized platelet-sized component in an isotonic, bacteriostatic medium. Fixed erythrocytes are added to simulate leukocytes.

STORAGE AND STABILITY

Boule Con-5Diff G2 Hematology Control is shipped in a thermally insulated container designed to keep it cool. When stored at 2-10° C, sealed vials are stable at least until the expiration date shown on the TABLE OF EXPECTED RESULTS.

Open vial stability 14 days after opening when returned to refrigerator after each use.

Storage of product with cap down (inverted) might require additional mixing for complete resuspension of cellular components.

INDICATIONS OF INSTABILITY OR DETERIORATION

Inability to obtain expected values may indicate product deterioration. Discoloration of the product may be caused by overheating or freezing during shipping or storage. Darkly colored supernatant may be indicative of product deterioration, however, moderately colored supernatant is normal and should not be confused with product deterioration. If the recovered values are not within the expected ranges:

1. Review the control product package insert and the operating procedure of the instrument.
2. Check the expiration date of the Boule Con-5Diff G2. Discard outdated products.
3. Test an additional unopened vial of Boule Con-5Diff G2.

INSTRUCTIONS FOR USE

1. Remove Boule Con-5Diff G2 Hematology Control from refrigeration and allow to warm at ambient temperature (18-32°C) for 10-15 minutes before mixing.
2. After warming, mix by hand as follows:
 - a. Roll the tube or vial slowly between the palms of the hands eight times in an upright position.
 - b. Invert the tube and slowly roll it between the palms eight times.
 - c. Continue to mix in this manner until all cells are completely suspended. Tubes stored for a long time may require extra mixing.
 - d. Gently invert the tube 8 times immediately before sampling.
 - e. Note: Use of a Mechanical Mixer is not recommended.
3. Follow instruction in User's Manual for each sampling mode.
4. After open sampling, carefully wipe the rim of the tube and inside of the cap with a lint-free tissue. Replace the cap ensuring it is on tight.
5. Return the tubes to the refrigerator within 30 minutes of testing.
6. Compare instrument values to those given in the TABLE OF EXPECTED RESULTS.

- a. The instrument is considered well maintained and operating correctly if: 95% of the recovered values fall within expected range. No more than three consecutive values exceed the expected range. Recovered values do not trend outside the expected range.

- b. Failure to achieve the conditions listed in 6a above may indicate instrument and/or control problems. To identify the source of the problem see investigational procedure section.
7. For consistency and best precision data, use the three levels of the cell control in the following order: abnormal low, normal, and abnormal high.
 8. Before expiration of the current lot, good laboratory practice requires that a new lot of cell control be analyzed in parallel with the existing lot until a laboratory mean is established on the new lot.

PERFORMANCE LIMITS

Individual laboratories should expect better precision than that shown in the expected range column. Refer to your Product Manual for performance characteristics of precision for your instrument.

PRECAUTIONS

- For In-Vitro diagnostic use.
- All human source material used to manufacture this product was non-reactive for antigens to Hepatitis B and negative by tests for antibodies to HIV (HIV-1, HIV-2) and Hepatitis C using techniques specified by the U.S. Food and Drug Administration. **Because no known test method can assure complete absence of human pathogens, this product should be handled with appropriate precautions.**
- This product should not be disposed in general waste, but should be disposed with infectious medical waste. Disposal by incineration is recommended.
- This product is intended for use as supplied. Adulteration by dilution or addition of any materials to the product as supplied invalidates any diagnostic use of the product.
- Controls are not to be used as calibrators.



INVESTIGATIONAL PROCEDURE

If you need help in resolving control recovery problems, call our customer service department. To provide faster handling of your inquiry, please have the following information available when you call:

- Expiration dates and lot numbers of all reagents, the control(s) in question and other levels of cell control that you use.
- Data supporting the problem for the lot number in question.
- Previous cell control lot numbers and the data you have for these previous lots.
- Data from a current reproducibility study (N=10) using a fresh whole blood specimen and performed according to your Product Manual.
- Data from your last instrument calibration.

ORDERING INFORMATION AND SERVICE

Contact your local distributor for orders and support. Please have the catalog number ready for orders. For other assistance contact Boule Medical AB at phone +46 8 7447700, fax +46 8 7447720 or info@boule.se

For translation of this instruction and explanation to symbols see www.quintus5part.com/support/downloads

Ordering no:	Description	Packaging
1504375	Boule Cal-5Diff G2	1 x 3 mL
1504376	Boule Con-5Diff G2 Tri	6 x 3 mL
1504382	Boule Con-5Diff G2 Low	1 x 3 mL
1504379	Boule Con-5Diff G2 Low	6 x 3 mL
1504381	Boule Con-5Diff G2 Norm	1 x 3 mL
1504378	Boule Con-5Diff G2 Norm	6 x 3 mL
1504380	Boule Con-5Diff G2 High	1 x 3 mL
1504377	Boule Con-5Diff G2 High	6 x 3 mL



Technical Document

14/ Boule Hypochlorite Cleaner



Product name: Boule Hypochlorite Cleaner

Article No: 1504385 (100mL)

Manufacturer: Boule Medical AB
Domnarvsgatan 4
SE-163 53 Spånga
Sweden

Telephone: 0046 8 744 77 00

Fax: 0046 8 744 77 20

Product Description: Boule Hypochlorite Cleaner is used for maintenance and cleaning of Quintus automated hematology analyzers.

Active Ingredients: Sodium hypochlorite for lipid/protein degradation 4-5 % active chlorine
Sodium hydroxide for stability < 0.5 %
Surfactants for cleaning < 1 %

Preservatives: The product contains no added anti-microbial substances since the hypochlorite and high pH will prevent growth of bacteria or molds.

Shelf life: **18 months from day of manufacture.** The shelf life of this product is based on accelerated and real-time stability studies. .

Storage: 15 - 30 °C (59 to 86 °F). The product can be shipped at ambient temperature but avoid freezing.

Packaging and Weight: 100 milliliter, ca 125 g weight with bottle

Warning and Precautions: Contains sodium hypochlorite and sodium hydroxide

The Hypochlorite 4% Cleaner is classified as hazardous to health and the environment according to CLP [Regulation (EC) no 1272/2008]. See product labeling below, detailed information is given in the Safety Data Sheet (SDS). A translation to the indicated languages of the hazard information is also available.

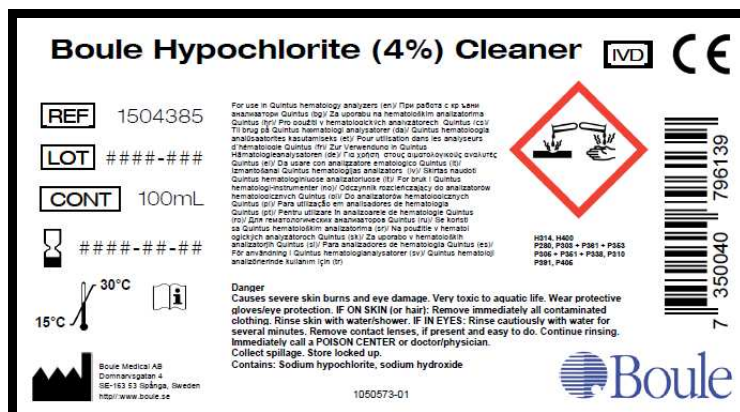
Instructions for use: Use in accordance with manufacturer's instructions for use (IFU).

Quality Control Specifications for Hypochlorite Cleaner:

Test	Specifications
pH	11.5-13.5
Hypochlorite concentration	4 – 5 %

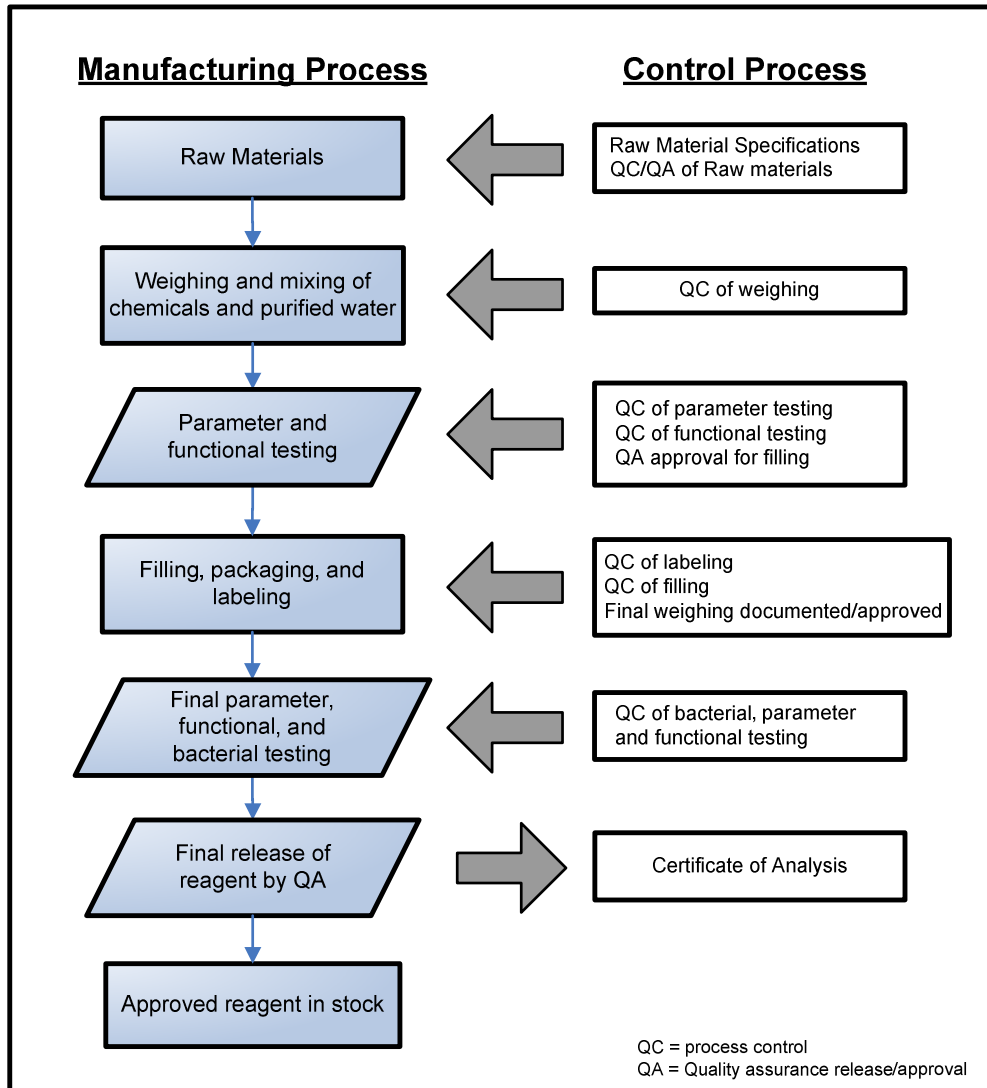
Product Conformity: Boule Hypochlorite Cleaner is in conformance with the 98/79/EC *In Vitro Diagnostic Medical Device Directive (IVD)* using Annex III as the conformity assessment procedure.

Product Labelling:



Manufacturing Process:

For the manufacturing process and the specific process control points for this reagent see the flowchart below. The process starts with raw materials for the manufacturing of the reagent being checked in by the content of certificates (e.g. Batch Specific Certificate of Analysis) against acceptance limits and by follow-up analysis of at least one specific characteristic chemical property (e.g. pH in solution). The process is completed with final QC parameter, functional, and bacterial testing, the release by QA accompanied by the Certificate of Analysis, and the approved product moved to stock.



Technical Document

1/ Medonic M-series Diluent



Product name	Medonic M-series Diluent	
Article No	1504122 (20 liter)	
Manufacturer	Boule Medical AB Domnarvsgatan 4 SE-163 53 Spånga, Sweden Telephone: 0046 8 744 77 00 Fax: 0046 8 744 77 20	
Country of origin	Sweden	
Product Description	Medonic M-series Diluent is a hematology diluent used for cell counting and sizing in the Medonic M-series automated, hematology analyzers.	
Active Ingredients	Salts for isotonic stability	< 2.0 %
	Antimicrobials	< 0.1 %
	Buffering agents	< 0.5 %
Preservatives	The stabilizing solution contains buffer salts with anti-microbial substances to prevent contamination of bacteria or molds, these substances are biodegradable.	
Shelf life	36 months from day of manufacture. The shelf life of this product is based on accelerated and real-time stability studies.	
Open container stability	3 months	
Storage	4-35 °C (39 to 95 °F). Avoid freezing.	
Packaging and Weight	20 liter (21.2 kg) LDPE cubitainer packed in cardboard box.	

Package and Labels

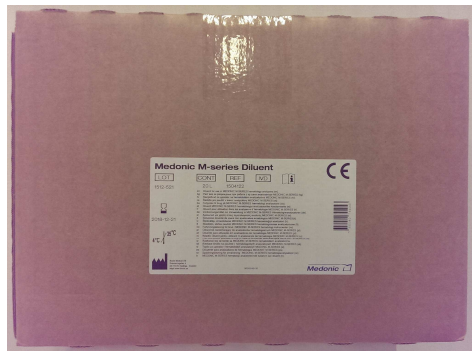


Figure 1 – Medonic M-series Diluent package

Contains Kathon. May produce an allergic reaction. (en)/Съдържа Kathon. Може да причини алергична реакция. (bg)/Sadrži Kathon. Može izazvati alergijsku reakciju. (hr)/Obsahuje Kathon. Může vyvolat alergickou reakci. (cs)/Inneholder Kathon. Kan udløse allergisk reaktion. (da)/Sisaldab Kathon. Võiib esile kutsuda allergilise reaktsiooni. (et)/Contient du Kathon. Peut produire une réaction allergique. (fr)/Enthält Kathon. Kann allergische reaktionen hervorrufen. (de)/Περιέχει Kathon. Μπορεί να προκαλέσει αλλεργική αντίδραση. (el)/Contiene Kathon. Può provocare una reazione allergica. (it)/Satur Kathon. Var izraisīt alergisku reakciju. (lv)/Sudėtyje yra Kathon. Gali sukelti alerginę reakciją. (lt)/Inneholder Kathon. Kan gi en allergisk reaksjon. (no)/Zawiera Kathon. Może powodować wystąpienie reakcji alergicznej. (pl)/Contém Kathon. Pode provocar uma reacção alérgica. (pt)/Conține Kathon. Poate provoca o reacție alergică. (ro)/Содержит Kathon. Может вызвать аллергическую реакцию. (ru)/Sadrzi Kathon. Može izazvati alergijsku reakciju. (sr)/Obsahuje Kathon. Může vyvolat' alergickou reakciu. (sk)/Vsebuje Kathon. Lahko povzroči alergijski odziv. (sl)/Contiene Kathon. Puede provocar una reacción alérgica. (es)/Innehåller Kathon. Kan orsaka en allergisk reaktion. (sv)/Kathon içerir. Alerjik reaksiyona neden olabilir. (tr)

EUH 208 Art.nr. 1050820 **Boule Medical AB**

Figure 2 – Additional CLP information

Medonic M-series Diluent

LOT CONT REF IVD

20 L 1504122

en Diluent for use in MEDONIC M-SERIES hematology analyzers (en).
 bg Разтвор за разреждане при работа с кръвни анализатори MEDONIC M-SERIES (bg).
 hr Razrjeđivač za uporabu na hematološkim analizatorima MEDONIC M-SERIES (hr).
 os Reditilo pro použiti v krvni analizatorji MEDONIC M-SERIES (os).
 da Fortyndet til brug på MEDONIC M-SERIES hematologi analyser (da).
 et Diluent MEDONIC M-SERIES hematoloogia analüsaatorites kasutamiseks (et).
 fr Diluant pour utilisation dans les analyseurs d'hématologie MEDONIC M-SERIES (fr).
 de Verdünnungsmittel zur Verwendung in MEDONIC M-SERIES Hämatologieanalysatoren (de).
 el Απολυτικό για χρήση στους αιματολογικούς αναλυτές MEDONIC M-SERIES (el).
 it Soluzione diluente da usare con analizzatore ematologico MEDONIC M-SERIES (it).
 lv Šķīdinātāju izmantošanai MEDONIC M-SERIES hematoloģijā analizatorī (lv).
 lt Skiediklis, skirtas naudoti MEDONIC M-SERIES hematologiniuose analizatoriuose (lt).
 no Fortynningsløsning for bruk i MEDONIC M-SERIES hematologi-instrumenter (no).
 pl Odczynnik rozcieńczalowy do analizatorów hematologicznych MEDONIC M-SERIES (pl).
 pt Diluente para utilização em analisadores de hematologia MEDONIC M-SERIES (pt).
 ro Reactiv Diluent pentru utilizare în analizoarele de hematologie MEDONIC M-SERIES (ro).
 ru Изотонический разбавитель для гематологических анализаторов MEDONIC M-SERIES (ru).
 sr Rastvarač koji se koristi sa MEDONIC M-SERIES hematološkim analizatorima (sr).
 sk Riediace činidlo na použitie v hematologických analyzátoroch MEDONIC M-SERIES (sk).
 sl Topilo za uporabo v hematoloških analizatorih MEDONIC M-SERIES (sl).
 es Diluyente para analizadores de hematología MEDONIC M-SERIES (es).
 sv Spädningslösning för användning i MEDONIC M-SERIES hematologi-analysatorer (sv).
 tr MEDONIC M-SERIES hematoloji analizörlerinde kullanılan içim dilüent (tr).

4°C 35°C

Boule Medical AB
Domnarvsgatan 4
SE-163 53 Spånga, Sweden
http://www.boule.se

1050248-10

Medonic

Figure 3 – Label on cardboard box

Recycling information

Part	Material	Weight (g)
Box	Cardboard	670
Politainer including cap	Plastic	230

Warning and Precautions

Not classified as hazardous according to CLP (EC regulation 1272/2008), information given on added label. Use good laboratory practice. Avoid contact with skin, eyes, and clothing. Do not swallow.

Instructions for use

Use in accordance with manufacturer's instructions for use and follow the Instrument User's Manual for connection and fill instruction.

Quality Control Specifications

Test	Specifications
pH	6.90 - 7.10
Osmolality (mOsm/kg)	290 - 310
Conductivity (mS/cm)	17.50 - 18.00
Background test (RBC, PLT)	Passed test
Total bacterial growth (CFU/100 ml)	≤ 5
Appearance	Clear, colorless liquid

Product Conformity

Directives	Standards/Comments
98/79/EEC In Vitro Diagnostic Medical Device Directive (IVD)	Using Annex III as the conformity assessment procedure

Precision Testing (Instrument)

Parameter	RBC	MCV	HGB	PLT	WBC
CV	≤ 1.8 %	≤ 1.5 %	≤ 1.5 %	≤ 4.8 %	≤ 3.5 %

Histograms

The measuring principles of the Medonic analyzers are based on impedance and spectrophotometry principles. The number of cells for determining RBC and WBC values are counted from a suspension of 1:40,000 for the RBC and 1:400 for the WBC dilution ratio of whole blood.

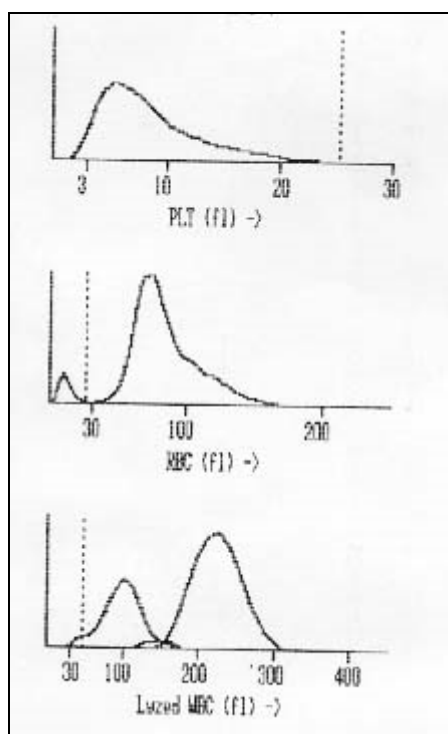


Figure 4 – Histograms for PLT, RBC and WBC

Manufacturing Process For the manufacturing process and the specific process control points for this reagent see the flowchart below. The process starts with raw materials for the manufacturing of the reagent being checked in by the content of certificates (e.g. Batch Specific Certificate of Analysis) against acceptance limits and by follow-up analysis of at least one specific characteristic chemical property (e.g. pH in solution). The process is completed with final QC parameter, functional, and bacterial testing, the release by QA accompanied by the Certificate of Analysis, and the approved reagent moved to stock.

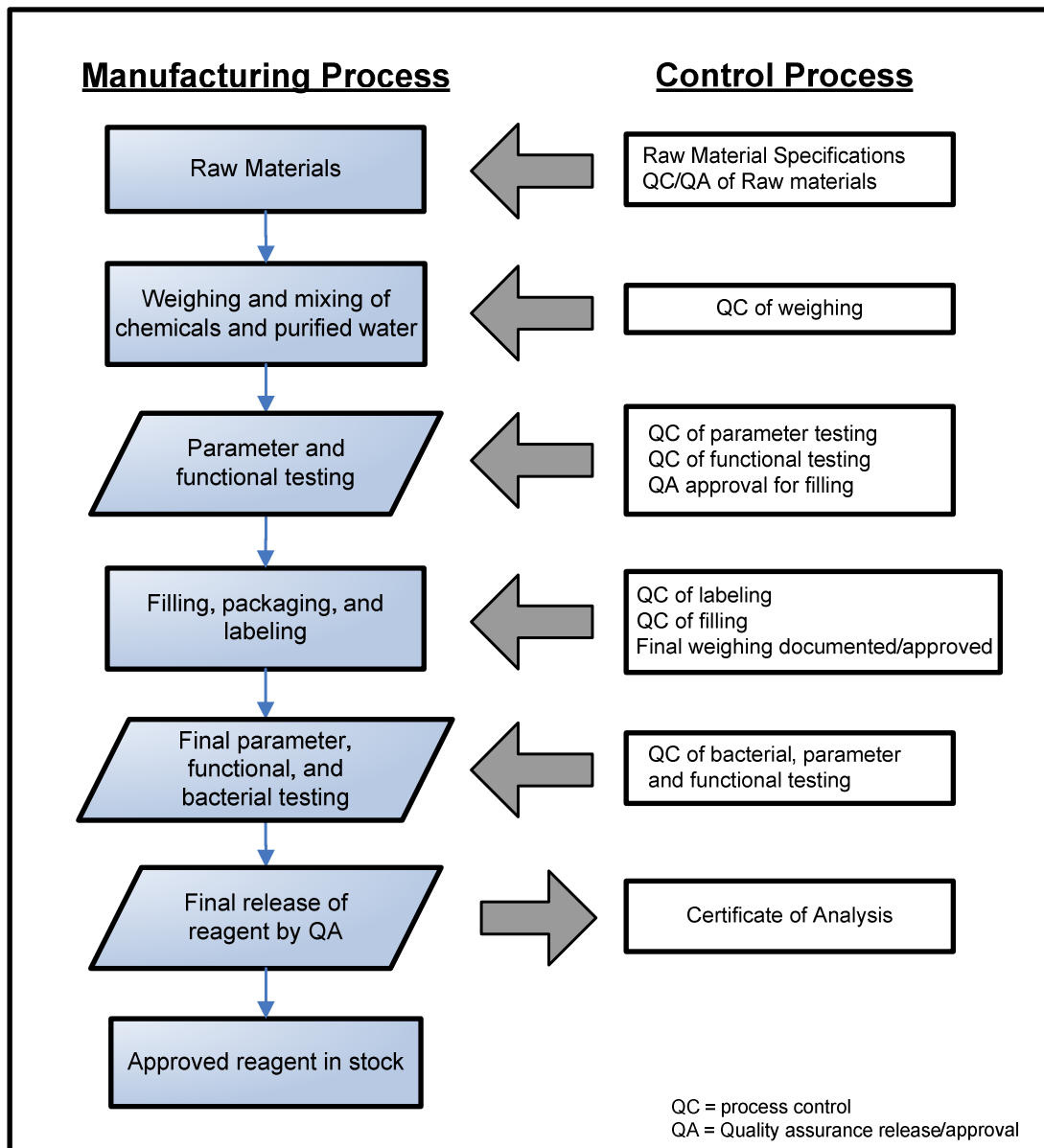


Figure 5 - Flow chart for manufacturing and quality control

Product name	Medonic M-series Lyse	
Article No	1504123 (5 liter)	
Manufacturer	Boule Medical AB Domnarvsgatan 4 SE-163 53 Spånga, Sweden Telephone: 0046 8 744 77 00 Fax: 0046 8 744 77 20	
Country of origin	Sweden	
Product Description	Medonic M-series Lyse is a cyanide-free hematology lytic reagent used for cell counting and sizing in the Medonic M-series, semi-automated and automated, hematology analyzers.	
Active Ingredients	Quaternary ammonium salts	< 0.5 %
	Salts	< 1.5 %
Shelf life	36 months from day of manufacture. The shelf life of this product is based on accelerated and real-time stability studies.	
Open container stability	3 months	
Storage	4-35 °C (39 to 95 °F). Avoid freezing.	
Packaging and Weight	5 liter (5.4 kg) LDPE cubitainer packed in cardboard box.	
Package and Labels		



Figure 1 – Medonic M-series Lyse package, polittainer in cardboard box

Contains Kathon. May produce an allergic reaction. (en)/Съдържа Kathon. Може да причини алергична реакция. (bg)/Sadrží Kathon. Може izazvati alergijsku reakciju. (hr)/Obsahuje Kathon. Může vyvolat alergickou reakci. (cs)/Indeholder Kathon. Kan udløse allergisk reaktion. (da)/Sisaldab Kathon. Võib esile kutsuda allergilise reaktsiooni. (et)/Contient du Kathon. Peut produire une réaction allergique. (fr)/Enthält Kathon. Kann allergische reaktionen hervorrufen. (de)/Περιέχει Kathon. Μπορεί να προκαλέσει αλλεργική αντίδραση. (el)/Contiene Kathon. Può provocare una reazione allergica. (it)/Satur Kathon. Var izraisīt alergisku reakciju. (lv)/Sudėtyje yra Kathon. Gali sukelti alerginę reakciją. (lt)/Inneholder Kathon. Kan gi en allergisk reaktion. (no)/Zawiera Kathon. Może powodować wystąpienie reakcji alergicznej. (pl)/Contém Kathon. Pode provocar uma reacção alérgica. (pt)/Conține Kathon. Poate provoca o reacție alergică. (ro)/Содержит Kathon. Может вызвать аллергическую реакцию. (ru)/Sadrží Kathon. Može izazvati alergijsku reakciju. (sr)/Obsahuje Kathon. Může vyvolat alergickou reakciu. (sk)/Vsebuje Kathon. Lahko povzroči alergijski odziv. (sl)/Contiene Kathon. Puede provocar una reacción alérgica. (es)/Innehåller Kathon. Kan orsaka en allergisk reaktion. (sv)/ Kathon içerir. Alerjik reaksiyona neden olabilir. (tr)

EUH 208 Art.Nr. 1050820 **Boule Medical AB**

Figure 2 – Additional CLP information

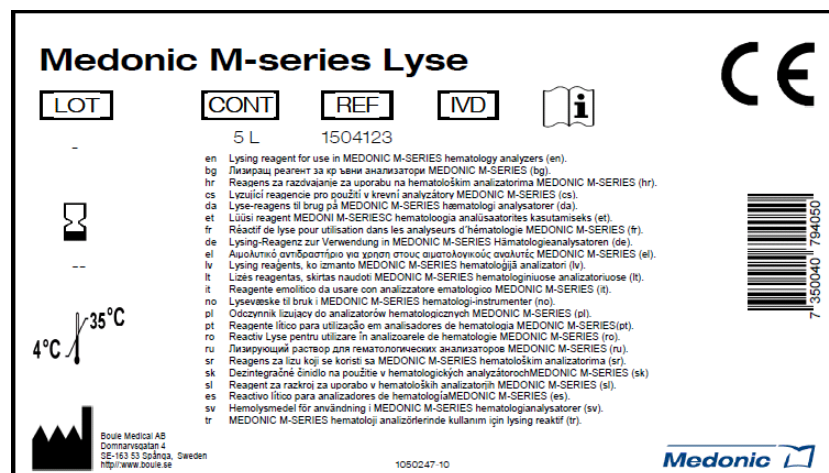


Figure 3 – Label on cardboard box

Recycling information

Part	Material	Weight (g)
Box	Cardboard	220
Politainer including cap	Plastic	100

Warning and Precautions

Not classified as hazardous according to CLP (EC regulation 1272/2008), information given on added label. Use good laboratory practice. Avoid contact with skin, eyes, and clothing. Do not swallow.

Instructions for use

Use in accordance with manufacturer's instructions for use and follow the Instrument User's Manual for connection and fill instruction.

Quality Control Specifications:

Test	Specifications
pH	7.0 ± 0.2
Osmolality (mOsm/kg)	230 ± 10
Conductivity (mS/cm)	14.5 ± 0.5
CBC Performance*	Passed test
Particles (PLT/RBC channel)	≤ 0.2
Total bacterial growth (CFU/100 ml)	≤ 5
Appearance	Clear, colorless liquid

*Performance test using calibrated blood cell counter at Boule Medical reference laboratory. All parameters except mid cells are tested. Accepted reference 95% to 105% of expected control blood sample values.

Product Conformity

Directives	Standards/Comments
98/79/EEC In Vitro Diagnostic Medical Device Directive (IVD)	Using Annex III as the conformity assessment procedure

Precision Testing (Instrument)

Parameter	RBC	MCV	HGB	PLT	WBC
CV	≤ 1.8 %	≤ 1.5 %	≤ 1.5 %	≤ 4.8 %	≤ 3.5 %

Histograms:

The measuring principles of the Medonic analyzers are based on impedance and spectrophotometry principles. The number of cells for determining RBC and WBC values are counted from a suspension of 1:40,000 for the RBC and 1:400 for the WBC dilution ratio of whole blood.

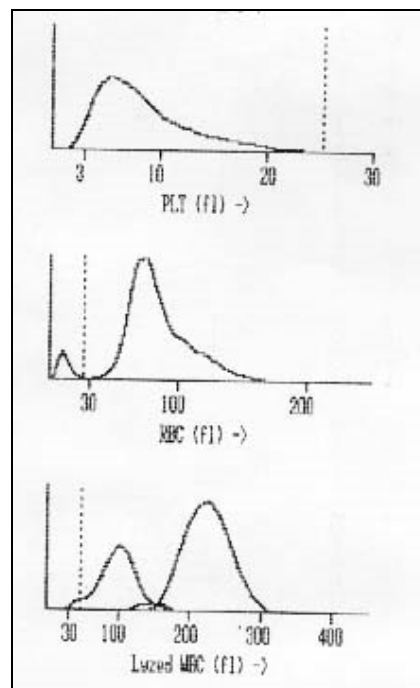


Figure 4 – Histograms for PLT, RBC and WBC

Manufacturing Process

For the manufacturing process and the specific process control points for this reagent see the flowchart below. The process starts with raw materials for the manufacturing of the reagent being checked in by the content of certificates (e.g. Batch Specific Certificate of Analysis) against acceptance limits and by follow-up analysis of at least one specific characteristic chemical property (e.g. pH in solution). The process is completed with final QC parameter, functional, and bacterial testing, the release by QA accompanied by the Certificate of Analysis, and the approved reagent moved to stock.

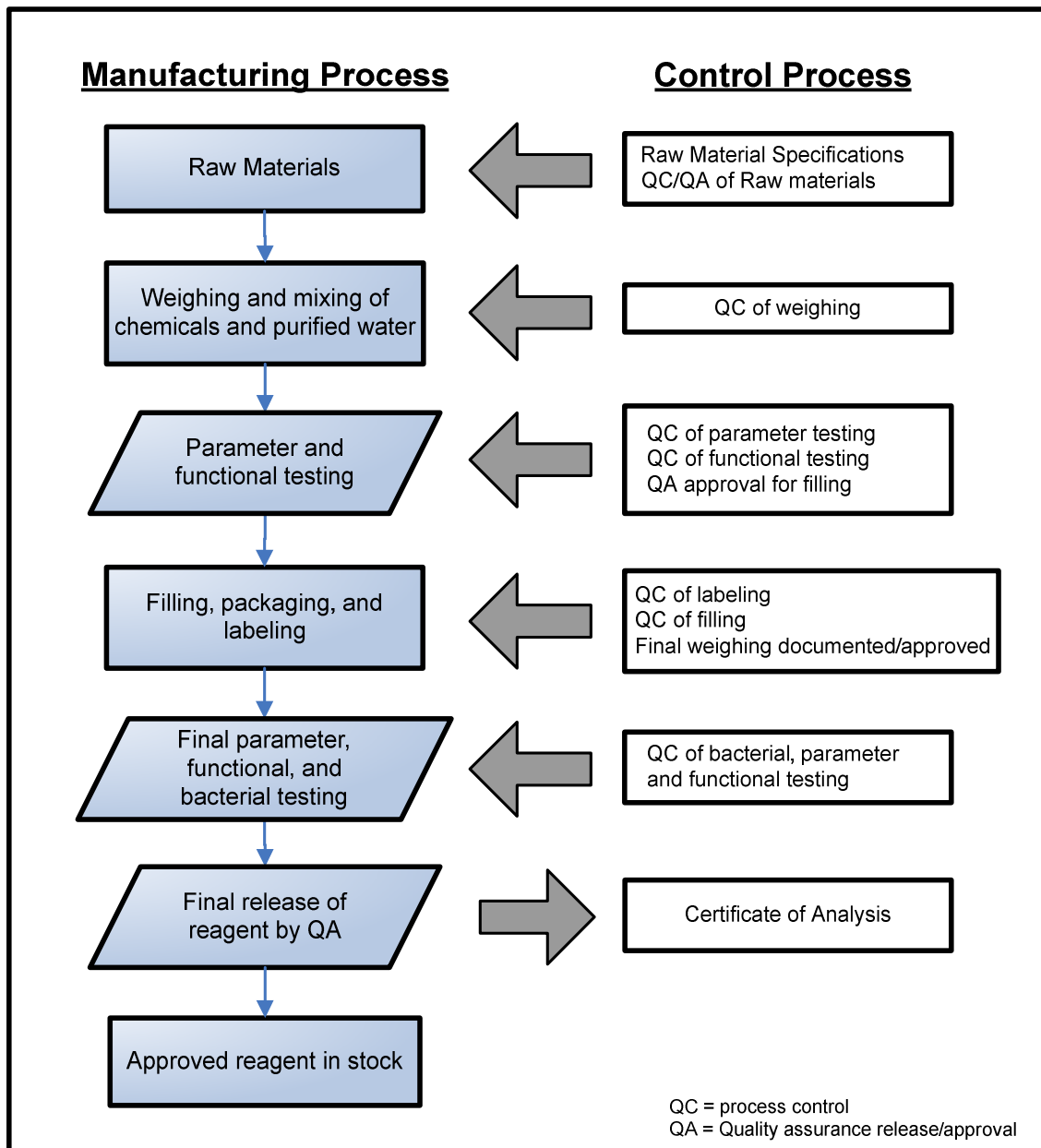


Figure 5 Flow chart for manufacturing and quality control

INTENDED USE

Boule Cal Hematology Calibrator is manufactured for calibration of multi-parameter hematology analyzers.

IVD

SUMMARY AND PRINCIPLES

Multi-parameter hematology analyzers require regular calibration in order to produce accurate results on patient samples. Calibration can be accomplished by transferring information to the analyzer through fresh blood samples, which have been assayed by reference methods. A more direct and convenient approach is to use a calibrator material with System Specific Values (SSV) assigned such as Boule Cal.

Boule Cal is a stable suspension of red blood cells, white blood cells and platelets. Assigned values are derived from replicate analyses on whole blood calibrated hematology analyzers (see reference procedures). A user analyzes Boule Cal on their instrument and computes calibration factors by comparing recovered values and assigned values. These factors provide the basis for making adjustments to the instrument.

REAGENTS

Boule Cal contains treated, stabilized human erythrocytes and a stabilized platelet-sized component in an isotonic, bacteriostatic medium. Fixed erythrocytes are added to simulate leukocytes.

STORAGE AND STABILITY

Boule Cal is shipped in a thermally insulated container designed to keep it cool. When stored at 2-10°C, sealed vials are stable at least until the expiration date shown on the TABLE OF EXPECTED RESULTS. Open Vial stability is 5 days after opening when returned to refrigerator after each use.

Storage of product with cap down (inverted) might require additional mixing for complete resuspension of cellular components.

INDICATION OF INSTABILITY OR DETERIORATION

Inability to obtain expected values may indicate product deterioration. Discoloration of the product may be caused by overheating or freezing during shipping or storage. Darkly colored supernatant may be indicative of product deterioration, however, moderately colored supernatant is normal and should not be confused with product deterioration. If the recovered values are not within the expected ranges:

1. Review the calibrator product package insert and the operating procedure of the instrument.
2. Check the expiration date of the Boule Cal. Discard outdated products.
3. Test an additional unopened vial of Boule Cal.

INSTRUCTIONS FOR USE

1. Remove Boule Calibrator from refrigeration and allow to warm at ambient temperature (18-32°C) for 10-15 minutes before mixing.
2. After warming, mix by hand as follows:
 - a. Roll the tube or vial slowly between the palms eight times in an upright position.
 - b. Invert the tube and slowly roll it between the palms eight times.
 - c. Continue to mix in this manner until all cells are completely suspended. Tubes stored for a long time may require extra mixing.
 - d. Gently invert the tube 8 times immediately before sampling.
 - e. Note: Use of a Mechanical Mixer is not recommended.
3. Refer to the User's manual for calibration procedure.
4. After open sampling, carefully wipe the rim of the tube and inside of the cap with a lint-free tissue. Replace the cap ensuring it is on tight.
5. Return the tubes to the refrigerator within 30 minutes of use.
6. For further assistance, please contact your local distributor.

PRECAUTIONS

- For In-Vitro diagnostic use.
- All human source material used to manufacture this product was non-reactive for antigens to Hepatitis B and negative by tests for antibodies to HIV (HIV-1, HIV-2) and Hepatitis C using techniques specified by the U.S. Food and Drug Administration. **Because no known test method can assure complete absence of human pathogens, this product should be handled with appropriate precautions.**
- This product should not be disposed in general waste, but should be disposed with infectious medical waste. Disposal by incineration is recommended.
- This product is intended for use as supplied. Adulteration by dilution or addition of any materials to the product as supplied invalidates any diagnostic use of the product.



REFERENCE PROCEDURES

WBC- A series of 1:500 dilutions are made using class A glassware. The lytic reagent is placed in the initial dilution flask before diluting to volume. The diluting agent is an isotonic solution for Beckman Coulter® instruments. The samples are counted on a Beckman Coulter Counter Z instrument.

RBC- A series of 1:50,000 dilutions are made using class A glassware. The diluting agent is an isotonic solution for Beckman Coulter® series instruments. The samples are counted on a Beckman Coulter Counter Z instrument.

Hgb- Hemoglobin concentration is determined by converting hemoglobin to hemiglobincyanide (HiCN) and measuring absorbance at 540 nm according to NCCLS H15-A2 and ICSH recommendations. Hemoglobin concentration is calculated using millimolar absorption coefficient of 11.0.

HCT- Microhematocrit values are done in replicate on each sample, with capillary tubes filled and centrifuged according to the NCCLS H7-A2 document. K3EDTA is used as the anticoagulant for collection of fresh specimens. The packed cell volume, or hematocrit, is read directly using a precision metric scale. No correction is made for trapped plasma.

Plt- A series of 1:125 macrodilutions are prepared using class A glassware in 1% Ammonium Oxalate. Charged hemacytometers are allowed to stand 20-30 minutes. Cells are counted using phase-contrast microscopy technique.

MPV- Based on a method using latex particles.

ORDERING INFORMATION AND SERVICE

Contact your local distributor for orders and support. Please have the catalog number ready for orders. For other assistance contact Boule Medical AB at phone +46 8 7447700, fax +46 8 7447720 or info@boule.se.

For translation of this instruction and explanation to symbols see www.medonic.se/ www.swelab.com/ /support/downloads

Ordering no:	Description	Packaging
1504025	Boule Cal	1 x 3.0 ml
1504045	Boule Cal	2 x 3.0 ml
1504022	Boule Con-Diff Tri-Level	16 parameter 6 x 4.5 ml
1504020	Boule Con-Diff Low	16 parameter 1 x 4.5 ml
1504176	Boule Con-Diff Low	16 parameter 6 x 4.5 ml
1504019	Boule Con-Diff Normal	16 parameter 1 x 4.5 ml
1504043	Boule Con-Diff Normal	16 parameter 6 x 4.5 ml
1504021	Boule Con-Diff High	16 parameter 1 x 4.5 ml
1504216	Boule Con-Diff High	16 parameter 6 x 4.5 ml
1504041	Boule Con-Diff Low	16 parameter 4.5 ml
1504040	Boule Con-Diff Normal	16 parameter 4.5 ml
1504042	Boule Con-Diff High	16 parameter 4.5 ml



INTENDED USE

For *in vitro* diagnostic use as a control to monitor the performance of multi-parameter hematology instruments.

IVD

SUMMARY AND PRINCIPLES

Boule Con Hematology Control is prepared from stabilized human blood so that repeated measurements can be made daily to monitor the performance of hematology analyzer systems. ASSIGNED VALUES and EXPECTED RANGES are determined on systems using specific Boule reagents. ASSIGNED VALUES are confirmed by multiple analysis of the control product and should be considered a **suggested average** until you establish your own running mean.

REAGENTS

Boule Con Hematology Control contains treated, stabilized human erythrocytes and a stabilized platelet-sized component in an isotonic, bacteriostatic medium. Fixed erythrocytes are added to simulate leukocytes.

STORAGE AND STABILITY

Boule Con Hematology Control is shipped in a thermally insulated container designed to keep it cool. When stored at 2-10° C, sealed vials are stable at least until the expiration date shown on the TABLE OF EXPECTED RESULTS. Open vial stability 14 days after opening when returned to refrigerator after each use.

Storage of product with cap down (inverted) might require additional mixing for complete resuspension of cellular components.

INDICATIONS OF INSTABILITY OR DETERIORATION

Inability to obtain expected values may indicate product deterioration. Discoloration of the product may be caused by overheating or freezing during shipping or storage. Darkly colored supernatant may be indicative of product deterioration, however, moderately colored supernatant is normal and should not be confused with product deterioration. If the recovered values are not within the expected ranges:

1. Review the control product package insert and the operating procedure of the instrument.
2. Check the expiration date of the Boule Con. Discard outdated products.
3. Test an additional unopened vial of Boule Con.

INSTRUCTIONS FOR USE

1. Remove Boule Con Hematology Control from refrigeration and allow to warm at ambient temperature (18-32°C) for 10-15 minutes before mixing.
2. After warming, mix by hand as follows:
 - a. Roll the tube or vial slowly between the palms of the hands eight times in an upright position.
 - b. Invert the tube and slowly roll it between the palms eight times.
 - c. Continue to mix in this manner until all cells are completely suspended. Tubes stored for a long time may require extra mixing.
 - d. Gently invert the tube 8 times immediately before sampling.
 - e. Note: Use of a Mechanical Mixer is not recommended.
3. Follow instruction in User's Manual for each sampling mode.
4. After open sampling, carefully wipe the rim of the tube and inside of the cap with a lint-free tissue. Replace the cap ensuring it is on tight.
5. Return the tubes to the refrigerator within 30 minutes of testing.
6. Compare instrument values to those given in the TABLE OF EXPECTED RESULTS.
 - a. The instrument is considered well maintained and operating correctly if: 95% of the recovered values fall within expected range. No more than three consecutive values exceed the expected range. Recovered values do not trend outside the expected range.

- b. Failure to achieve the conditions listed in 6a above may indicate instrument and/or control problems. To identify the source of the problem see investigational procedure section.

7. For consistency and best precision data, use the three levels of the cell control in the following order: abnormal low, normal, and abnormal high.
8. Before expiration of the current lot, good laboratory practice requires that a new lot of cell control be analyzed in parallel with the existing lot until a laboratory mean is established on the new lot.

PERFORMANCE LIMITS

Individual laboratories should expect better precision than that shown in the expected range column. Refer to your Product Manual for performance characteristics of precision for your instrument.

PRECAUTIONS



- For In-Vitro diagnostic use.
- All human source material used to manufacture this product was non-reactive for antigens to Hepatitis B and negative by tests for antibodies to HIV (HIV-1, HIV-2) and Hepatitis C using techniques specified by the U.S. Food and Drug Administration. **Because no known test method can assure complete absence of human pathogens, this product should be handled with appropriate precautions.**
- This product should not be disposed in general waste, but should be disposed with infectious medical waste. Disposal by incineration is recommended.
- This product is intended for use as supplied. Adulteration by dilution or addition of any materials to the product as supplied invalidates any diagnostic use of the product.
- Controls are not to be used as calibrators.

INVESTIGATIONAL PROCEDURE

If you need help in resolving control recovery problems, call our customer service department. To provide faster handling of your inquiry, please have the following information available when you call:

- Expiration dates and lot numbers of all reagents, the control(s) in question and other levels of cell control that you use.
- Data supporting the problem for the lot number in question.
- Previous cell control lot numbers and the data you have for these previous lots.
- Data from a current reproducibility study (N=10) using a fresh whole blood specimen and performed according to your Product Manual.
- Data from your last instrument calibration.

ORDERING INFORMATION AND SERVICE

Contact your local distributor for orders and support. Please have the catalog number ready for orders. For other assistance contact Boule Medical AB at phone +46 8 7447700, fax +46 8 7447720 or info@boule.se

For translation of this instruction and explanation to symbols see www.medonic.se/ www.swelab.com/ /support/downloads

Ordering no:	Description	Packaging
1504025	Boule Cal	1 x 3.0 ml
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1504043	Boule Con-Diff Normal	16 parameter 6 x 4.5 ml
1504021	Boule Con-Diff High	16 parameter 1 x 4.5 ml
1504216	Boule Con-Diff High	16 parameter 6 x 4.5 ml
1504041	Boule Con-Diff Low	16 parameter 4.5 ml
1504040	Boule Con-Diff Normal	16 parameter 4.5 ml
1504042	Boule Con-Diff High	16 parameter 4.5 ml

Product name	Boule Cleaning Kit	
Article No	1504111:	Boule Enzymatic Cleaner 450 mL Boule Hypochlorite (2%) Cleaner 450 mL Boule Detergent Cleaner 450 mL
Manufacturer	Boule Medical AB Domnarvsgatan 4 SE-163 53 Spånga, Sweden Telephone: 0046 8 744 77 00 Fax: 0046 8 744 77 20	
Country of origin	Sweden	
Product Description	Boule Cleaning Kit is combination pack used for maintenance and cleaning of Medonic CA620/530, Medonic M-series, Swelab AC920/970, Swelab Alfa Series and Exigo automated hematology analyzers.	
Active Ingredients	<p><u>Enzymatic Cleaner:</u> Subtilisin for proteolytic action < 0.1 % Surfactants < 0.2 % Stabilizers incl. salts and buffers < 2 % Coloring substances << 0.1 %</p> <p><u>Hypochlorite 2% Cleaner:</u> Sodium hypochlorite for lipid/protein degradation 2.0 – 2.4 % active chlorine Sodium hydroxide for stability < 0.05 % Surfactants < 0.05%</p> <p><u>Detergent Cleaner:</u> Sodium dodecyl sulfate for protein dissociation < 0.1 % Surfactants < 0.2 % Stabilizers incl. salts and buffers < 1 % Coloring substances << 0.1 %</p>	
Preservatives	The stabilizing solution contains buffer salts with anti-microbial substances to prevent contamination of bacteria or molds.	
Shelf life	24 months from day of manufacture. The shelf life of this product is based on accelerated and real-time stability studies.	
Open container stability	Until expiry date	
Storage	4 - 30 °C (59 to 86 °F). Avoid freezing.	
Packaging and Weight	3 x 450 milliliter (1.6 kg) bottles packed in a cardboard box	
Package and Labels		



Figure 1 – Cardboard box



Figure 2 - Label on cardboard box

Contains Kathon. May produce an allergic reaction. (en)Съдържа Kathon. Може да причини алергична реакция. (bg)Sadrži Kathon. Može izazvati alergijsku reakciju. (hr)Obsahuje Kathon. Može vyvolat alergickou reakci. (cs)Inneholder Kathon. Kan utlöse allergisk reaktion. (da)Sisaldab Kathon. Võib esile kutsuda allergilise reaktsiooni. (et)Contient du Kathon. Peut produire une réaction allergique. (fr)Enthält Kathon. Kann allergische reaktionen hervorrufen. (de)Περιέχει Kathon. Μπορεί να προκαλέσει αλλεργική αντίδραση. (el)Contiene Kathon. Puede provocar una reacción alérgica. (it)Satur Kathon. Var izraisīt alergisku reakciju. (lv)Sudėtyje yra Kathon. Gali sukelti alerginę reakciją. (lt)Inneholder Kathon. Kan gi en allergisk reaktion. (no)Zawiera Kathon. Może powodować wystąpienie reakcji alergicznej. (pl)Contém Kathon. Pode provocar uma reação alérgica. (pt)Contine Kathon. Poate provoca o reacție alergică. (ro)Содержит Kathon. Может вызвать аллергическую реакцию. (ru)Sadrži Kathon. Može izazvati alergijsku reakciju. (sr)Obsahuje Kathon. Može vyvolat' alergickú reakciu. (sk)Vsebuje Kathon. Lahko povzroči alergijsko odziv. (sl)Contiene Kathon. Puede provocar una reacción alérgica. (es)Innehåller Kathon. Kan orsaka en allergisk reaktion. (sv)Kathon içerir. Alerjik reaksiyona neden olabilir. (tr)

EUH 208 Art.Nr. 1050820 **Boule Medical AB**

Figure 3 - Additional CLP information

Safety data sheet available on request. (en)Информационен лист за безопасност ще бъде представен при поискване. (bg)Sigurnosno-tehnički list dostupan na zahtjev. (hr)Na vyzádání je kodispozici bezpečnostní list. (cs)Sikkerhedsdatablad kan på anmodning rekvireres. (da)Ohutuskaart nõudmisel kättesaadav. (et)Fiche de données de sécurité disponible sur demande. (fr)Sicherheitsdatenblatt auf Anfrage erhältlich. (de)Δελτίο δεδομένων ασφαλείας παρέχεται εφόσον ζητηθεί. (el)Schema dati di sicurezza disponibile su richiesta. (it)Drošības datu lapa ir pieejama pēc pieprasījuma. (lv)Saugos duomenų lapą galima gauti paprašius. (lt)Sikkerhedsdatablad er tilgjengelig på anmodning. (no)Karta karakteristiki dostupna na žądanie. (pl)Ficha de segurança fornecida a pedido. (pt)Fişa cu date de securitate disponibilă la cerere. (ro)Паспорт безопасности предоставляется по запросу. (ru)Bezbednosni list dostupan na zahtev. (sr)Na požiadanie možno poskytnúť kartu bezpečnostných údajov. (sk)Varnosti list na voljo na zahtevo. (sl)Puede solicitarse la ficha de datos de seguridad. (es)Säkerhetsdatablad finns att rekvirera. (sv)Istec üzerine Güvenlik Bilgi Formu. (tr)

EUH210 Art.Nr. 1050821 **Boule Medical AB**

Figure 4 – Information SDS

Immediate container

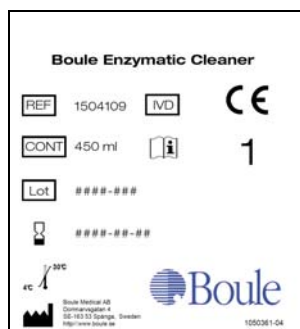


Figure 5 - Bottle and label Enzymatic Cleaner

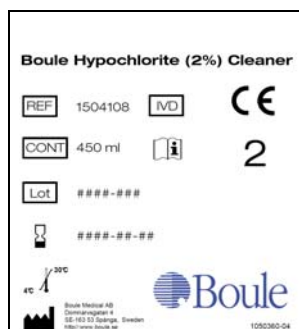


Figure 6 – Bottle and label Hypochlorite (2%) Cleaner

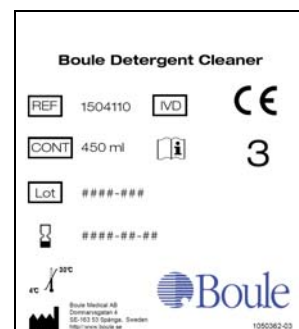


Figure 7 – Bottle and label Detergent Cleaner

Recycling information

Part	Material	Weight (g)
Box	Cardboard	84
Bottle 450mL x3	Plastic	40 each

Warning and Precautions

Not classified as hazardous according to CLP (EC regulation 1272/2008), information given on added labels. Use good laboratory practice. Avoid contact with skin, eyes, and clothing. Do not swallow. See SDS for further information.

Instructions for use

Use in accordance with manufacturer's instructions for use.

Quality Control Specifications for Enzymatic Cleaner

Test	Specifications
pH	7.6 – 8.4
Particles (PLT/RBC channel)	PLT < 100 x 10 ⁹ /L RBC < 0.05 x 10 ¹² /L

Quality Control Specifications for Hypochlorite Cleaner

Test	Specifications
Hypochlorite concentration	2.0 – 2.4 %
Particles (PLT/RBC channel)	PLT < 100 x 10 ⁹ /L RBC < 0.05 x 10 ¹² /L

Quality Control Specifications for Detergent Cleaner

Test	Specifications
pH	7.6 – 8.4
Particles (PLT/RBC channel)	PLT < 100 x 10 ⁹ /L RBC < 0.05 x 10 ¹² /L

Product Conformity

Directives	Standards/Comments
98/79/EEC In Vitro Diagnostic Medical Device Directive (IVD)	Using Annex III as the conformity assessment procedure
1907/2006/EC Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH),	
1272/2008/EC classification, labelling and packaging of substances and mixtures (CLP)	

Manufacturing Process

For the manufacturing process and the specific process control points for this reagent see the flowchart below. The process starts with raw materials for the manufacturing of the reagent being checked in by the content of certificates (e.g. Batch Specific Certificate of Analysis) against acceptance limits and by follow-up analysis of at least one specific characteristic chemical property (e.g. pH in solution). The process is completed with final QC parameter, functional, and bacterial testing, the release by QA accompanied by the Certificate of Analysis, and the approved product moved to stock.

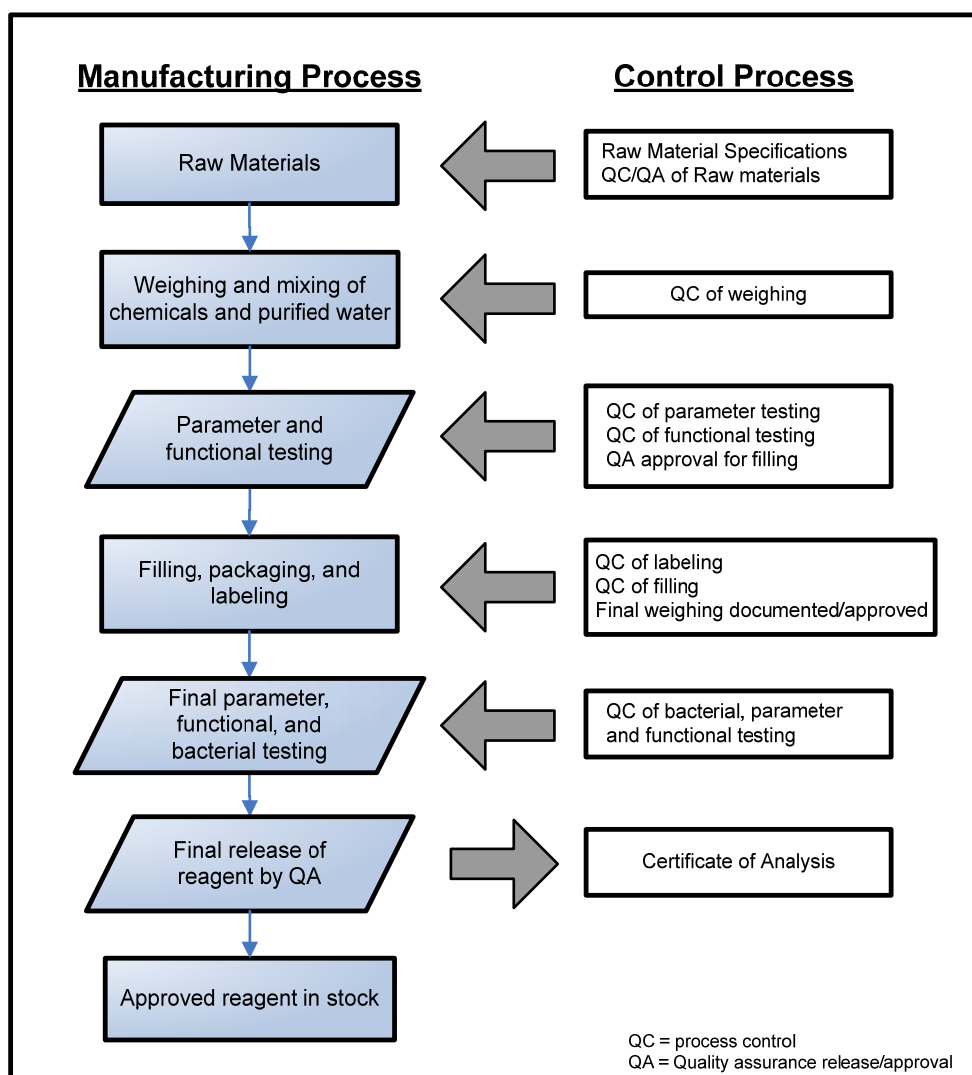


Figure 8 – Flow Chart Manufacturing and Quality Control

Product name	Boule Enzymatic Cleaner	
Article No	1504112 (100 ml)	
Manufacturer	Boule Medical AB Domnarvsgatan 4 SE-163 53 Spånga, Sweden Telephone: 0046 8 744 77 00 Fax: 0046 8 744 77 20	
Country of origin	Sweden	
Product Description	Boule Enzymatic Cleaner is used for maintenance and cleaning of Medonic CA620/530, Medonic M-series, Swelab AC920/970, Swelab Alfa Series and Exigo automated, hematology analyzers.	
Active Ingredients	Subtilisin for proteolytic action	< 0.1 %
	Surfactants	< 0.2 %
	Stabilizers incl. salts and buffers	< 2 %
	Coloring substances	<< 0.1 %
Preservatives	The stabilizing solution contains buffer salts with anti-microbial substances to prevent contamination of bacteria or molds, these substances are biodegradable.	
Shelf life	24 months from day of manufacture. The shelf life of this product is based on accelerated and real-time stability studies.	
Open container stability	Until expiry date	
Storage	4 - 30 °C (39 to 86 °F). Avoid freezing.	
Packaging and weight	118 g total weight	
Instructions for use	Use in accordance with manufacturer's instructions for use.	
Package and Labels		



Figure 1 - 100 milliliter, plastic bottle

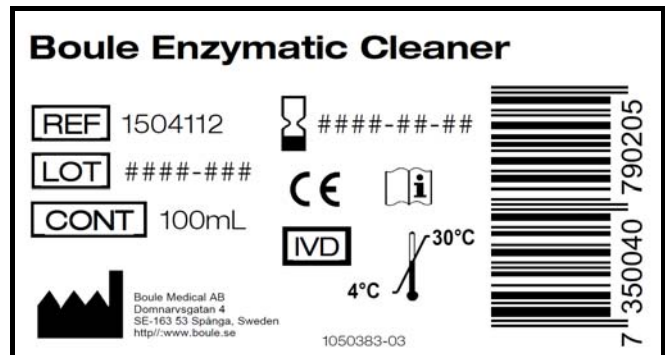


Figure 2 - Label on bottle

Contains Kathon. May produce an allergic reaction. (en)/Съдържа Kathon. Може да причини алергична реакция. (bg)/Sadrží Kathon. Může izazvati alergijsku reakciju. (hr)/Obsahuje Kathon. Může vyvolat alergickou reakci. (cs)/Inneholder Kathon. Kan utlösa allergisk reaktion. (da)/Sisaldab Kathon. Võib esile kutsuda allergilise reaktsiooni. (et)/Contient du Kathon. Peut produire une réaction allergique. (fr)/Enthält Kathon. Kann allergische reaktionen hervorrufen. (de)/Περιέχει Kathon. Μπορεί να προκαλέσει αλλεργική αντίδραση. (el)/Contiene Kathon. Può provocare una reazione allergica. (it)/Satur Kathon. Var izraisīt alergisku reakciju. (lv)/Sudėtyje yra Kathon. Gali sukelti alergine reakciją. (lt)/Inneholder Kathon. Kan gi en allergisk reaktion. (no)/Zawiera Kathon. Może powodować wystąpienie reakcji alergicznej. (pl)/Contiém Kathon. Pode provocar uma reacção alérgica. (pt)/Contiene Kathon. Pote provocar o reacție alergică. (ro)/Содержит Kathon. Может вызвать аллергическую реакцию. (ru)/Sadrží Kathon. Může izazvati alergijsku reakciju. (sk)/Vsebuje Kathon. Lahko povzroči alergijski odziv. (sl)/Contiene Kathon. Puede provocar una reacción alérgica. (es)/Innehåller Kathon. Kan orsaka en allergisk reaktion. (sv)/ Kathon içerir. Alerjik reaksiyona neden olabilir. (tr)

EUH 208 Art.nr. 1050820 **Boule Medical AB**

Figure 3 - Additional CLP information

Safety data sheet available on request. (en)/Информационен лист за безопасност ще бъде представен при поискване. (bg)/Sigurnosno-tehnički list dostupan na zahtjev. (hr)/Na vyžádání je k dispozici bezpečnostní list. (cs)/Sikkerhedsdatablad kan på anmodning revireres. (da)/Ohutuskaart nõudmisel kättesaadav. (et)/Fiche de données de sécurité disponible sur demande. (fr)/Sicherheitsdatenblatt auf Anfrage erhältlich. (de)/Δεξιο δεδομένων ασφαλείας παρέχεται εφόσον ζητηθεί. (el)/Scheda dati di sicurezza disponibile su richiesta. (it)/Drošības datu lapa ir pieejama pēc pieprasījuma. (lv)/Saugos duomenų lapą galima gauti paprasčiaus. (lt)/Sikkerhedsdatablad er tilgjengelig på anmodning. (no)/Karta karakteristyktyki dostępa na żądanie. (pl)/Ficha de segurança fornecida a pedido. (Pt)/Fişa cu date de securitate disponibilă la cerere. (ro)/Паспорт безопасности предоставляется по запросу. (ru)/Bezbednosni list dostupan na zahtev. (sr)/Na požiadanie možno poskytnúť kartu bezpečnostných údajov. (sk)/Varnosti list na voljo na zahtevo. (sl)/Puede solicitarse la ficha de datos de seguridad. (es)/Säkerhetsdatablad finns att rekvirera. (sv)/İstek üzerine Güvenlik Bilgi Formu. (tr)

EUH210 Art.nr. 1050821 **Boule Medical AB**

Figure 4 – Information SDS

Recycling information

Part	Material	Weight (g)
Bottle	Plastic	16

Warning and Precautions

Not classified as hazardous according to CLP (EC regulation 1272/2008), information given on added labels. Use good laboratory practice. Avoid contact with skin, eyes, and clothing. Do not swallow. See SDS for further information

Instructions for use

Use in accordance with manufacturer's instructions for use and follow Operator manual for connection and fill instruction.

Quality Control Specifications

Test	Specifications
pH	7.6 – 8.4
Particles (PLT/RBC channel)	PLT < 100 x 10 ⁹ /L RBC < 0.05 x 10 ¹² /L

Product Conformity

Directives	Standards/Comments
98/79/EEC In Vitro Diagnostic Medical Device Directive (IVD)	Using Annex III as the conformity assessment procedure
1907/2006/EC Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH),	
1272/2008/EC classification, labelling and packaging of substances and mixtures (CLP)	

Manufacturing Process

For the manufacturing process and the specific process control points for this reagent see the flowchart below. The process starts with raw materials for the manufacturing of the reagent being checked in by the content of certificates (e.g. Batch Specific Certificate of Analysis) against acceptance limits and by follow-up analysis of at least one specific characteristic chemical property (e.g. pH in solution). The process is completed with final QC parameter, functional, and bacterial testing, the release by QA accompanied by the Certificate of Analysis, and the approved product moved to stock.



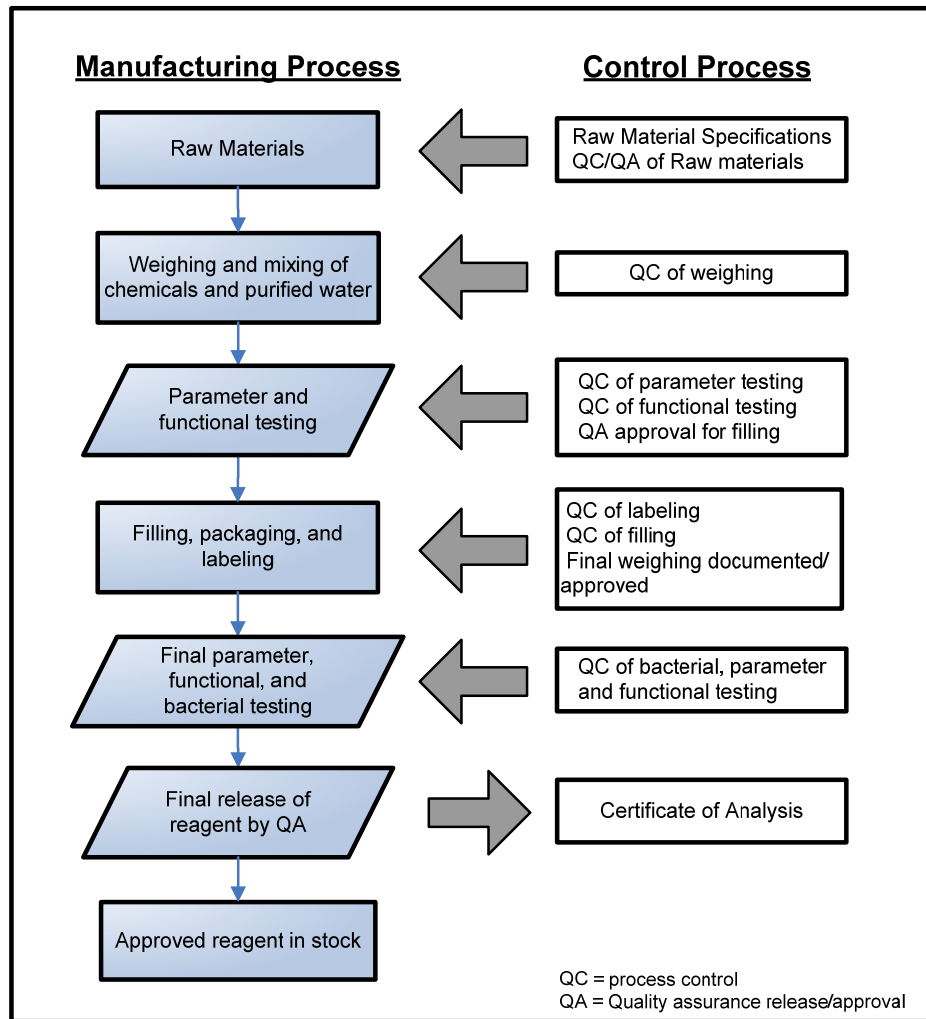


Figure 5 - Flow Chart Manufacturing and Quality Control

Technical Document

9/ Boule Hypochlorite 2% Cleaner



Product name	Boule Hypochlorite 2% Cleaner
Article No	1504113 (500mL)
Manufacturer	Boule Medical AB Domnarvsgatan 4 SE-163 53 Spånga, Sweden Telephone: 0046 8 744 77 00 Fax: 0046 8 744 77 20
Country of origin	Sweden
Product Description	Boule Hypochlorite Cleaner is used for maintenance and cleaning of Medonic CA620/530, Medonic M-series, Swelab AC920/970, Swelab Alfa Series and Exigo automated, hematology analyzers.
Active Ingredients	Sodium hypochlorite for lipid/protein degradation 2.0 – 2.4 % active chlorine Sodium hydroxide for stability < 0.05 % Surfactants < 0.05%
Preservatives	The stabilizing solution contains buffer salts but no added anti-microbial substances since the hypochlorite and high pH will prevent growth of bacteria or molds.
Instructions for use	Use in accordance with manufacturer's instructions for use.
Storage	4 - 30 °C (39 to 86 °F). Avoid freezing.
Shelf life	24 months from day of manufacture. The shelf life of this product is based on accelerated and real-time stability studies.
Open container stability	Until expiry date
Packaging and Weight	500 milliliter (545 g) plastic bottle
Package and Label	



Figure 1 - 500 mL plastic bottle

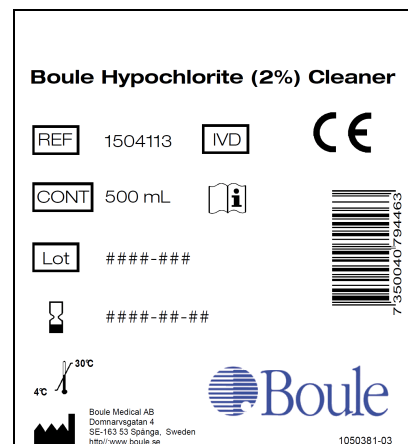


Figure 2 – Label on bottle

Safety data sheet available on request. (en)/Информационен лист за безопасност ще бъде представен при поискване. (bg)/Sigurnosno-tehnički list dostupan na zahtjev. (hr)/Na vyžádání je kodispozici bezpečnostní list. (cs)/Sikkerhedsdatablad kan på anmodning rekvireres. (da)/Ohutuskaart nõudmisel kättesaadav. (et)/Fiche de données de sécurité disponible sur demande. (fr)/Sicherheitsdatenblatt auf Anfrage erhältlich. (de)/Δεδομένο ασφαλείας παρέχεται εφόσον ζητηθεί. (el)/Scheda dati di sicurezza disponibile su richiesta. (it)/Drošības datu lapa ir pieejama pēc pieprasījuma. (lv)/Saugos duomenų lapą galima gauti paprašius. (lt)/Sikkerhedsdatablad er tilgjengelig på anmodning. (no)/Karta karakterystyki dostępna na żądanie. (pl)/Ficha de siguranță furnecida a pedido. (Pt)/Ficha cu date de securitate disponibilă la cerere. (ro)/Паспорт безопасности предоставляется по запросу. (ru)/Bezbednosni list dostupan na zahtev. (sr)/Na požiadanje možno poskytnúť kartu bezpečnostných údajov. (sk)/Varnosti list na voljo na zahtevo. (sl)/Puede solicitarse la ficha de datos de seguridad. (es)/Säkerhetsdatablad finns att rekvirera. (sv)/Istek užerine Güvenlik Bilgi Formu. (tr)

EUH210 Art.Nr. 1050821 **Boule Medical AB**

Figure 3 – Information SDS

Recycling information

Part	Material	Weight (g)
Bottle	Plastic	40

Warning and Precautions

Not classified as hazardous according to CLP (EC regulation 1272/2008), information given on added label. Use good laboratory practice. Avoid contact with skin, eyes, and clothing. Do not swallow. See SDS for additional information.

Quality Control Specifications

Test	Specifications
pH	11.5 – 12.1
Hypochlorite concentration	2.0 – 2.4 %
Particles (PLT/RBC channel)	PLT < 100 x 10 ⁹ /L RBC < 0.05 x 10 ¹² /L

Product Conformity

Directives	Standards/Comments
98/79/EEC In Vitro Diagnostic Medical Device Directive (IVD)	Using Annex III as the conformity assessment procedure

Manufacturing Process

For the manufacturing process and the specific process control points for this reagent see the flowchart below. The process starts with raw materials for the manufacturing of the reagent being checked in by the content of certificates (e.g. Batch Specific Certificate of Analysis) against acceptance limits and by follow-up analysis of at least one specific characteristic chemical property (e.g. pH in solution). The process is completed with final QC parameter, functional, and bacterial testing, the release by QA accompanied by the Certificate of Analysis, and the approved product moved to stock.

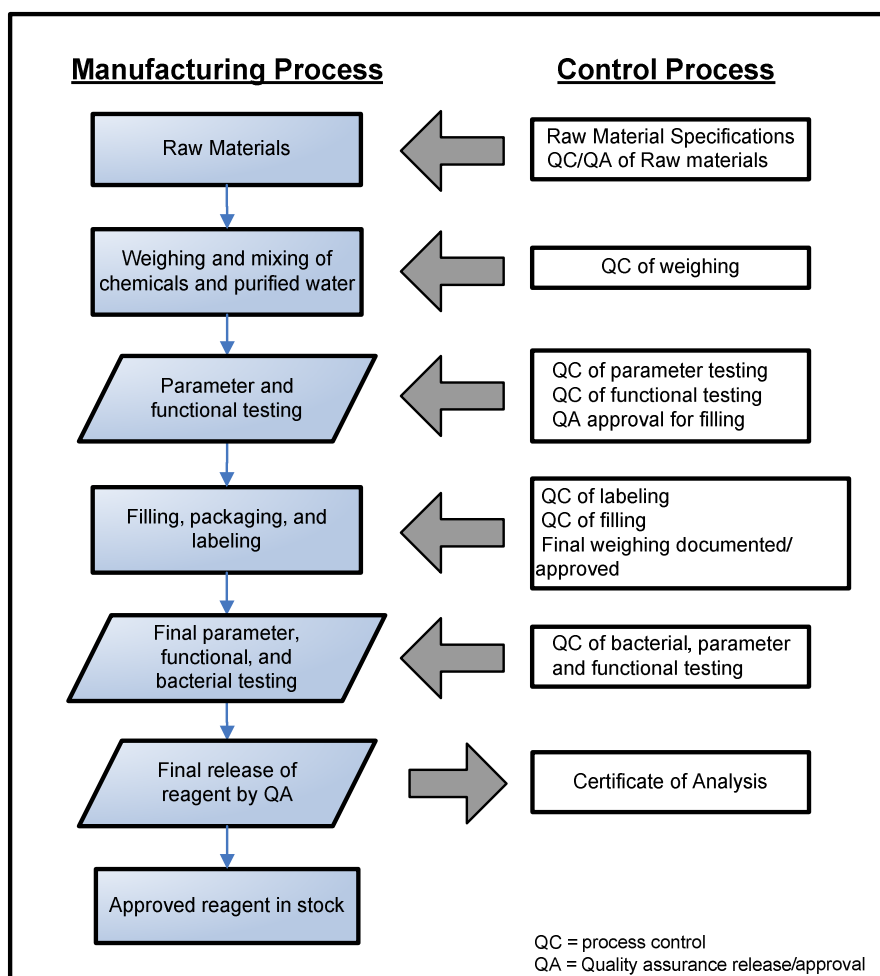


Figure 4 – Flow chart Manufacturing and Quality Control



Technical Document

Micropipette, Plastic EDTA 20µL



Product name Micropipette 20µL, plastic

Article No 1070030 Micropipette Plastic EDTA 20µL 10x100 pcs/crt
1070039 Micropipette Plastic EDTA 20 µL 1x100pcs

Manufacturer Boule Medical AB
Domnarvsgatan 4
SE-163 53 Spånga, Sweden
Telephone: 0046 8 744 77 00
Fax: 0046 8 744 77 20

Country of origin Sweden, Germany

Product Description The product 1070030 consists of:

Name	Quantity	Part number
Micropipette 20µL x 100 pcs	10	1070039
Label, product	10	N/A
Label, cardboard box	1	N/A
Cardboard box for package	1	N/A

Shelf life **36 months from day of manufacture.** The shelf life of this product is based on actual test results in real-time studies.

Open container stability Until expiry date

Storage 2-30 °C (36 to 86 °F)

Technical specification Micropipette 20µL, dimensions:

Outer diameter:	1.76 mm	± 0.03 mm	
Length:	27.5 mm	± 1 mm	
Volume:	20 µL	R: ≤ 0.5%	CV: ≤ 1.0%
Treatment:	EDTA (K2)	35 - 70 µg per micropipette	

Intended use For laboratory use only (in vitro diagnostic). The micropipette is intended for blood collection from a finger stick or venous sample and direct inserted into the MPA/MCI inlet of Medonic CA620/530/Medonic M-series and Swelab Alfa automated, hematology analyzers

Instructions for use Use in accordance to instructions in Medonic CA620/530/M-series and Swelab Alfa User Manuals.

Quality Control

- All micropipettes are manufactured with the proper plastic collection.
- All micropipettes contain the correct additive in proper quality.
- In-process and finished product QC checks assure that all capillary tubes are properly constructed, there are 100 finished micropipettes in a dispenser box, all dispenser boxes are properly sealed and labeled.

Product Conformity

- Boule Micropipette, Plastic EDTA 20µL is in conformance with the *98/79/EC In Vitro Diagnostic Medical Device Directive (IVD)* using Annex III as the conformity assessment procedure.
- 1907/2006/EC Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH),
- 1272/2008/EC classification, labelling and packaging of substances and mixtures (CLP)



Technical Document

Micropipette, Plastic EDTA 20µL

Weight 160g, 10x100 package including cardboard box
13g, 1x100 package, no outer box

Recycling information

Part	Material	Weight (g)
Box	Cardboard	32
Container	Plastic	6 each

Package

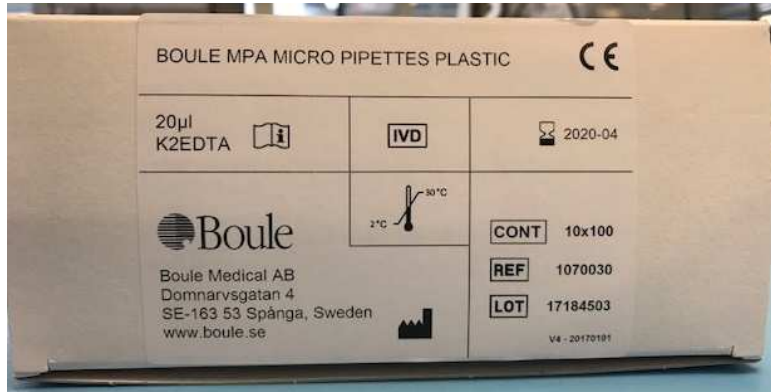


Figure 1 – Package 1070030, 10x100

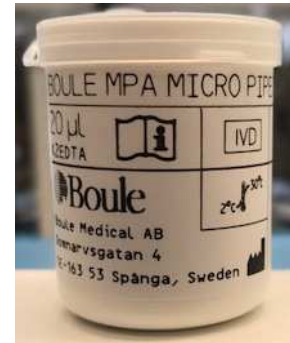


Figure 2 – Package 1070039, 1x100

Label

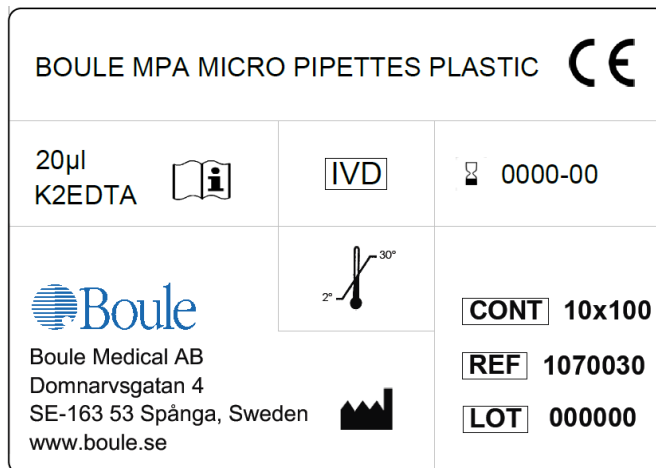


Figure 3 – Label on 10x100 package

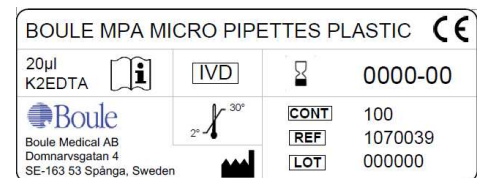


Figure 4 – Label on 1x100 package