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Declaration of Conformity

This Declaration of Conformity, issued under our sole responsibility, is only valid when the IVD is used in accordance with the instructions for use.

Manufacturer's Name: **Thermo Shandon Limited (Trading as Thermo Fisher Scientific)**

Brand Name: Thermo Scientific

Manufacturer's Address: Tudor Road
Manor Park
Runcorn
Cheshire
WA7 1TA
UNITED KINGDOM

Product Description: Sliding Microtome

Product Name: Thermo Scientific Sliding Microtome HM430

Product Common Name: HM430, HM 430

Part Number: 910010
accessories: 152020, 152030, 152040, 152070, 152080, 152090, 152050, 152160, 152100, 152200, 152215, 152230, 152240, 152250, 152260, 152270, 152280, 152570, 440400, 440410, 448070, 705200, 705340, 705430, 705440, 715480, 715500

Year of CE Marking: 2016

This product conforms to the essential requirements and meets all the applicable requirements of the following directive:

In Vitro Diagnostic Directive 98/79/EC in accordance with Annex III (Section 6 Excluded) and ISO 13485 Quality Assurance System (Full)
General IVD

Certificate of RoHS Compliance Directive 2011/65/EU on the restriction of use of certain hazardous substances in electrical and electronic equipment

Issued by:

Ruth Moss
Regulatory Affairs Manager
Anatomical Pathology Division
Thermo Fisher Scientific

Date: 26 July 2016.

Issue no: 01

ThermoFisher SCIENTIFIC

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Declaration of Conformity

This Declaration of Conformity, issued under our sole responsibility, is only valid when the IVD is used in accordance with the instructions for use.

Manufacturer's Name: **Thermo Shandon Limited (Trading as Thermo Fisher Scientific)**

Brand Name: Thermo Scientific

Manufacturer's Address: Tudor Road
Manor Park
Runcorn
Cheshire
WA7 1TA
UNITED KINGDOM

Product Description: Sliding Microtome

Product Name: Thermo Scientific Sliding Microtome HM450

Product Common Name: HM450, HM 450

Part Number: 910020
accessories: 440400, 440410, 448070, 705200, 705340, 70543, 705440, 715480, 715500
Additional equipment: 152010, 152030, 152040, 152050, 152020, 152060, 152070, 152080, 152090, 152100, 152220, 152230, 152240, 152250, 152260, 152270, 152280, 3053835, 3052835, 3051835, 3050835, 3050822, 3153735, 3151735

Year of CE Marking: 2016

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Issued by:

Ruth Moss
Regulatory Affairs Manager
Anatomical Pathology Division
Thermo Fisher Scientific

Date: 26 July 2016.

Issue no: 01

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Declaration of Conformity

This Declaration of Conformity, issued under our sole responsibility, is only valid when the IVD is used in accordance with the instructions for use.

Manufacturer's Name: **Thermo Shandon Limited (Trading as Thermo Fisher Scientific)**

Brand Name: Thermo Scientific

Manufacturer's Address: Tudor Road
Manor Park
Runcorn
Cheshire
WA7 1TA
UNITED KINGDOM

Product Description: Rotary Microtome

Product Name: Thermo Scientific Rotary Microtome HM340E

Product Common Name: HM 340E, HM340E

Part Number: 905190
Coolcut with universal cassette clamp: 771110
Coolcut with standard cassette clamp: 771120
Section transfer system: 771200, 715550, 575170
accessories: 152020, 152030, 152060, 152270, 176010, 705800, 705810, 705820, 705830, 715010, 715020, 715030, 715060, 715070, 715080, 715090, 715100, 715280, 715320, 715590, 716120, 716130, 716150
Additional accessories: 760160, 760170, 755210, 532090, 760340, 152200, 152215, 152570, 152070, 152080, 152220, 152230, 152240, 152280, 350110, 350120,

Year of CE Marking: 2016

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In Vitro Diagnostic Directive — 98/79/EC in accordance with Annex III (Section 6 Excluded) and ISO 13485 Quality Assurance System (Full)
General IVD

Certificate of RoHS Compliance — Directive 2011/65/EU on the restriction of use of certain hazardous substances in electrical and electronic equipment

Issued by:

Ruth Moss
Regulatory Affairs Manager
Anatomical Pathology Division
Thermo Fisher Scientific

Date: 27 July 2016.

Issue no: 01

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Declaration of Conformity

This Declaration of Conformity, issued under our sole responsibility, is only valid when the IVD is used in accordance with the instructions for use.

Manufacturer's Name: **Thermo Shandon Limited (Trading as Thermo Fisher Scientific)**

Brand Name: Thermo Scientific

Manufacturer's Address: Tudor Road
Manor Park
Runcorn
Cheshire
WA7 1TA
UNITED KINGDOM

Product Description: Rotary Microtome

Product Name: Thermo Scientific Rotary Microtome HM355S

Product Common Name: HM 355S, HM355S

Part Number: 905200
Coolcut with universal cassette clamp: 771110
Coolcut with standard cassette clamp: 771120
Section transfer system: 771200, 715550, 575170
accessories: 176010, 705800, 705810, 705820, 705830, 715010, 715020, 715030, 715060, 715070, 715080, 715090, 715100, 715280, 715320, 715590, 716120, 716130, 716150
Additional equipment: 152020, 152030, 152070, 152080 152120, 152200, 152215, 152220, 152230, 152240, 152270, 152280, 152570, 532090, 755210, 760160, 760170, 760340, 350110, 350120
Year of CE Marking: 2016

This product conforms to the essential requirements and meets all the applicable requirements of the following directive:

In Vitro Diagnostic Directive 98/79/EC in accordance with Annex III (Section 6 Excluded) and ISO 13485 Quality Assurance System (Full)
General IVD

Certificate of RoHS Compliance Directive 2011/65/EU on the restriction of use of certain hazardous substances in electrical and electronic equipment

Issued by:

Ruth Moss
Regulatory Affairs Manager
Anatomical Pathology Division
Thermo Fisher Scientific

Date: 26 July 2016

Issue no: 01

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Declaration of Conformity

This Declaration of Conformity, issued under our sole responsibility, is only valid when the IVD is used in accordance with the instructions for use.

Manufacturer's Name: **Thermo Shandon Limited (Trading as Thermo Fisher Scientific)**

Brand Name: Thermo Scientific

Manufacturer's Address: Tudor Road
Manor Park
Runcorn
Cheshire
WA7 1TA
UNITED KINGDOM

Product Description: Rotary Microtome

Product Name: Thermo Scientific Rotary Microtome HM 325

Product Common Name: HM 325, HM325

Part Number: 902100, 901140
Coolcut with universal cassette clamp: 771110
Coolcut with standard cassette clamp: 771120
Section transfer system: 771200, 715550, 575170
accessories: 152020, 152030, 152070, 152080, 152120, 152220, 152215, 152230, 152240, 152270, 152570, 176010, 350170, 532090, 565310, 602020, 602030, 705010, 705040, 705050, 705400, 705660, 705670, 715010, 715020, 715030, 715060, 715070, 715080, 715090, 715100, 715280, 715320, 715590, 716120, 716130, 716150, 755210, 760160, 760280, 760290, 760170
additional accessories: 350110, 350120

Year of CE Marking: 2016

This product conforms to the essential requirements and meets all the applicable requirements of the following directive:

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General IVD

Certificate of RoHS Compliance — Directive 2011/65/EU on the restriction of use of certain hazardous substances in electrical and electronic equipment

Issued by: RM Moss

Ruth Moss
Regulatory Affairs Manager
Anatomical Pathology Division
Thermo Fisher Scientific

Issue no: 02

Date:

ThermoFisher SCIENTIFIC

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Declaration of Conformity

This Declaration of Conformity, issued under our sole responsibility, is only valid when the IVD is used in accordance with the instructions for use.

Manufacturer's Name: **Thermo Shandon Limited (Trading as Thermo Fisher Scientific)**

Brand Name: Thermo Scientific

Manufacturer's Address: Tudor Road
Manor Park
Runcorn
Cheshire
WA7 1TA
UNITED KINGDOM

Product Description: Cryostat

Product Name: Thermo Scientific CryoStar NX70

Product Common Name: NX70

Part Number: 956960, 956970, 956980, 956990, 957000, 957010, 957020, 957030, 957040, 957050, 957060, 957070

accessories: 6502, 6506, 175200, 242530, 281000, 313940, 313960, 334000, 334170, 334180, 336080, 336090, 350110, 350120, 350270, 362260, 362010, 410540, 419500, 435560, 449980, 512990, 524510, 570380, 570390, 570400, 640380, 705840, 705940, 705950, 715530, 715600, 715610, 715620, 715870, 715880, 715890, 715900, 6769006, A78930078

Year of CE Marking: 2016

This product conforms to the essential requirements and meets all the applicable requirements of the following directive:

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General IVD

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Issued by:

Ruth Moss
Regulatory Affairs Manager
Anatomical Pathology Division
Thermo Fisher Scientific

Date: 26 July 2016

Issue no: 01

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Declaration of Conformity

This Declaration of Conformity, issued under our sole responsibility, is only valid when the IVD is used in accordance with the instructions for use.

Manufacturer's Name: **Thermo Shandon Limited (Trading as Thermo Fisher Scientific)**

Brand Name: Thermo Scientific

Manufacturer's Address: Tudor Road
Manor Park
Runcorn
Cheshire
WA7 1TA
UNITED KINGDOM

Product Description: Cryostat

Product Name: Thermo Scientific CryoStar NX50

Product Common Name: NX50

Part Number: 957180, 957080, 957190, 957090, 957250, 957100, 957270, 957120, 957260, 957110, 957230, 957130, 957220, 957140, 957210, 957150, 957200, 957160, 957170, 957240

accessories: 175200, 202180, 242530, 281000, 313940, 313960, 334160, 334171, 334172, 336080, 336090, 362260, 362120, 410540, 419500, 435560, 449980, 460380, 512990, 524510, 570380, 570390, 570400, 705840, 705940, 705950, 715530, 715600, 715870, 715880, 715890, 715900, 715610, 715620

Additional equipment: 334220, 334240, 612050

Year of CE Marking: 2016

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In Vitro Diagnostic Directive — 98/79/EC in accordance with Annex III (Section 6 Excluded) and ISO 13485 Quality Assurance System (Full)
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Issued by:

Ruth Moss
Regulatory Affairs Manager
Anatomical Pathology Division
Thermo Fisher Scientific

Date: 26 July 2016.

Issue no: 01

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Manufacturer's Name: **Thermo Shandon Limited (Trading as Thermo Fisher Scientific)**

Brand Name: Thermo Scientific

Manufacturer's Address: Tudor Road
Manor Park
Runcorn
Cheshire
WA7 1TA
UNITED KINGDOM

Product Description: Cryostat

Product Name: Thermo Scientific HM525 NX

Product Common Name: HM525 NX, HM525NX

Part Number: 956640, 956641, 956650, 956651
accessories: 334169, 334170, 362120, 362260, 362741, 415600, 415620, 415640, 432770, 432780, 570110, 715110
additional equipment: 449980, 449990, 524510, 570380, 570390, 570400, 705460, 705470, 705630, 715220, 715230, 715700, 715730, 715740, 715750, 715760

Year of CE Marking: 2016

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Issued by:

Ruth Moss
Regulatory Affairs Manager
Anatomical Pathology Division
Thermo Fisher Scientific

Date: 22 December 2016.

Issue no: 02