COOPDECH

EC DECLARATION OF CONFORMITY

CE01-K01-011

Manufacturer: DAIKEN MEDICAL CO., LTD.
2-6-2, Ayumino, Izumi-city, Osaka 594-1157, Japan

European Representative: Medical Technology Promedt Consulting GmbH,
Altenhofstrasse 80, D-66386 St. Ingbert, Germany

Facilities: DAIKEN MEDICAL CO., LTD.
2-6-2, Ayumino, Izumi-city, Osaka 594-1157, Japan
Fukudakougyo,Inc (Ayabe factory)
3, Ohshima-cho Sakajiri, Ayabe-city, Kyoto 623-0046, Japan
Fukudakougyo,Inc (Head office factory)
1-12, Syodaitajika, Hirakata-city, Osaka 573-1132, Japan
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6, Shiroyama-cho, Ayabe-city, Kyoto, 623-003, Japan
YANO ELECTRONICS (THAILAND) LTD.
207 Moo 7, Tambol Tatoom Amphur Srimahaphot, Prachinburi, 25140, Thailand

We, DAIKEN MEDICAL CO.LTD, do hereby declare that the medical devices, cited below, conform of the requirements of the Medical Devices Directive "93/42/EEC" and Annex 1.

Name: Coopdech Fit Fix
Product group: Canisters, Aspirator Collection (10-211)
Model(s)/Type(s): DKI-RD862P-EU, DKI-RD862F-EU, DKI-FF861-EU, DKI-FF2863P-EU, DKI-FF2863F-EU, DKI-RD2862P-EU, DKI-RD2862F-EU, DKI-FF2861-EU, DKI-FF707 (H/L)-EU, DKI-FF708H-EU, DKI-FF765-EU, DKI-FF767-EU, DKI-FF7301-EU, DKI-RD730P-EU, DKI-RD730F-EU, DKI-FF7303-EU,
Accessories: Caster, Hook, Wall Hanging set, Canister, Trestle set, Adapter, Three way stopcock, Nipple with bowl valve, Flow stopper, Solidifying agent unit
Class: Class I (Annex IX Rule 1)
Applied approach: Annex VII of Medical Devices Directive "93/42/EEC"

Products covered :

Document Number	title	Number of products
QMCK01-100	COOPDECH Fit Fix Device Master File	—
F-EN03-01-00 (FF)	Quality Standard (Product Standard) (Model: FITFIX)	—
FKR-BD5002	COOPDECH Fit Fix Device Master File	—
QQD000-067	COOPDECH Fit Fix Quality records	each Lot Number

Lot Number: FYYMMDDX
(F- FitFix , YY—year, MM—month, DD-day, X—specification)

This Declaration of conformity is valid in connection with the release document for the respective batch of produced device.

CÔNG TY TRÁCH NHIỆM HỮU HẠN Y TẾ ALFRESA CODUPHA VIỆT NAM

TỔNG GIÁM ĐỐC
YAMAMOTO HAJIME

Standards applied:

EN 980:2008	Symbols for use in the labelling of medical devices
EN 1041:2008	Information supplied by the manufacturer with medical devices
EN ISO10079-3:2009	Medical suction equipment – Part 3: Suction equipment powered from a vacuum or pressure source (ISO 10079-3:1999)
EN ISO 13485:2012	Medical devices – Quality management systems – Requirements for regulatory purposes (ISO 13485: 2003)
EN ISO 13485:2012/AC:2012	Medical devices – Quality management systems – Requirements for regulatory purposes (ISO 13485: 2003)
EN ISO 14971:2012	Medical devices – Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01)
EN 62366:2008	Medical devices – Application of usability engineering to medical devices (IEC 62366:2007)
MEDDEV2.7.1	Rev.3 Clinical Evaluation – A Guide for Manufacturers and Notified Bodies (December 2009)

Modification to the devices without prior approval from the undersigned will render this declaration null and void. This declaration of conformity and the "Technical Documentation" required by the directive will be on file at the manufacturer.

Place of declaration: DAIKEN MEDICAL CO., LTD.
2-6-2, Ayumino, Izumi-city, Osaka 594-1157, Japan

Date of declaration: 2014/7/25

Signature:
(Authorized person)

Hiroaki Takimoto
Quality Assurance Manager