

EC DECLARATION OF CONFORMITY

MANUFACTURER: SparMED APS / CVR. No.: 30898575,
Ryttermarken 2, DK-3520, Farum, Denmark

PRODUCTS: *Oosafe® Disinfectant*

CLASSIFICATION: Class IIa, Rule 15:

Non-active medical devices for disinfecting, cleaning and rinsing of all non-invasive medical instruments

CONFORMITY ASSESSMENT: Annex II of Directive MDD 93/42/EEC

Hereby, I the authorized representative of SparMED ApS, declare that the above listed products conform to the Council Directive 93/42/EEC for Medical Devices as transposed to the Danish laws.

NOTIFIED BODY:

Name: Istituto di Ricerche e Collaudi M. Masini S.r.l
Via Moscova 11, 20017
Rho (MI), Italy

Notified Body No: **NB 0068**

Applicable Standards:

ISO 13485: 2012

ISO 14971:2012-

EN 14885:2015-

ISO 10993-1:2009-

EN 62366-1:2015-

EN 1041:2008+A1:2013-

ISO 15223-1:2012

Medical devices- Quality Management Systems- Requirements for Regulatory Purposes

Medical Devices - Application of risk management to medical devices;

Chemical disinfectants and antiseptics. Application of European Standards for chemical disinfectants and antiseptics;

Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process;

Medical devices – Part 1: Application of usability engineering to medical devices;

Information supplied by the manufacturer of medical devices;

Medical devices- Symbols to be used with medical device labels, labelling and information to be supplied. Part 1: General Requirements.;

NAME / POSITION:

Onur Ozturk/ Director

DATE: 01.06.2016

SIGNATURE

