

EC CERTIFICATE

Number: 2146741CE01

Production Quality Assurance

Directive 93/42/EEC on Medical devices, Annex V

(Devices in Class I in sterile conditions and sterilised systems or procedure packs)

Manufacturer:

X-Flow BV

**Marssteden 50
7547 TC Enschede
The Netherlands**

For the product category(ies)

Medical Shower Filter and Medical Tap Filter to filter water to minimize waterborne infections in the hospital environment.

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EC-Directive which apply to them:

0344

Documents, that form the basis of this certificate:

Certification Notice 2146741CN, initially dated 7 September 2012

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Council Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments. The manufacturer has implemented a quality assurance system, that covers the aspects of manufacture concerned with securing and maintaining sterile conditions, for the above mentioned product category in accordance to the provisions of Annex V Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance.

The necessary information related to the quality assurance system of the manufacturer, including facilities and the reference to the relevant documentation, of the products concerned and the assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 1 September 2023
Issued for the first time: 7 September 2012
Reissued: 4 September 2018

DEKRA Certification B.V.



drs. G.J. Zoetbrood
Managing Director



J.A. van Vugt
Certification Manager

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DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra-certification.com Company registration 09085396