

QUALITY SYSTEM

EC-CERTIFICATE

Directive 93/42/EEC

Manufacturer: Franke Medical Oy
Vartiokuja 1
FI-76850 Naarajärvi
Finland

Coverage of Certificate: Design, manufacture and final inspection

Product category: Washers and disinfectors for
treating of medical materials

Valid until: 13th June 2020

The manufacturer's quality system for the design, manufacture and final inspection of the aforesaid product category has been evaluated and meets the provisions of Council Directive 93/42/EEC as set out in Annex II Section 3. This approval is valid until the expiry date provided that the manufacturer fulfils the obligations imposed by Annex II in Directive 93/42/EEC. Products covered by the certificate are specified in the attachment(s).

Tampere, 13th June 2015


Mikko Soikkeli

Certificate no.




VTT-C-11338-01-1035-542-15




Tuomas Toivonen

Notified Body no. 0537:
VTT Expert Services Ltd.
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Attachment 1 to the Certificate number: VTT-C-11338-01-1035-542-15

Manufacturer:	Franke Medical Oy Vartiokuja 1, FI-76850 Naarajärvi Finland			
Activity and product category:	Design, manufacture and final inspection of washers and disinfectors for treating of medical materials GMDN-code: 35424			
Products:	The certificate covers the following products:			
	<i>Name</i>	<i>Brand name</i>	<i>Model</i>	<i>Class</i>
	Washer Disinfector	Franke	Deko 25	IIa
	Washer Disinfector	Franke	Deko 190	IIa
	Washer Disinfector	Franke	Deko 260	IIa
	Washer Disinfector	Franke	Deko 2000	IIa
	Washer Disinfector	Franke	Deko D32	IIa
	Washer Disinfector	Franke	Deko D4	IIa
Date:	Tampere, 13 th June 2015.			
	  Mikko Soikkeli  Thomas Toivonen			

VTT Expert Services Ltd is Notified Body no. 0537 under Council Directive 93/42/EEC.