

QUALITY SYSTEM

**EC-CERTIFICATE**

Directive 93/42/EEC

Manufacturer: Franke Finland 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 2015

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. This Certificate is based on decision no. VTT-C-5648-01-1035-400-10-P0.

Tampere, 13<sup>th</sup> June 2010

  
Kaarle Kylmä

Certificate no.  
VTT-C-5648-01-1035-400-10






  
Seppo Lavonen

Notified Body no. 0537:  
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## DECISION

on a quality system and product range covered, based on Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, Annex II, Section 3.

Decision no.:	<b>VTT-C-5648-01-1035-400-10-P0</b> Extension of the validity period.
Manufacturer:	Franke Finland Oy Vartiokuja 1, FI-76850 Naarajärvi, Finland
Date of application:	28.5.2010
Activity and product category:	Design, manufacture and final inspection of washers and disinfectors for treating of medical materials
Decision:	A certificate will be issued to the manufacturer. The certificate covers the following products: <ul style="list-style-type: none"> <li>• Deko 25, class IIa</li> <li>• Deko 190, class IIa</li> <li>• Deko 260, class IIa</li> <li>• Deko 2000, class IIa</li> <li>• Deko D32, class IIa</li> <li>• Deko D4, class IIa</li> </ul>
Justification:	The manufacturer's certificate no. VTT-C-1849-01-1035-289-07 expires 13 <sup>th</sup> June 2010. The manufacturer's quality system has been reassessed and VTT Expert Services Ltd has found that the quality system and the products meet the requirements of Annex II of Medical Device Directive 93/42/EEC in design, manufacture and final inspection. The decision is based on the audit report no. NB-1035-A10. The company has signed the undertaking to follow the obligations of Annex II of the Directive.
Certificate related to decision:	VTT-C-5648-01-1035-400-10
Valid until:	This decision is valid until 13 <sup>th</sup> June 2015 unless the validity of the related certificate is changed.
Date:	Tampere, 13 <sup>th</sup> June 2010
	 <div style="display: flex; justify-content: space-around; margin-top: 20px;"> <div style="text-align: center;">   Kaarle Kylmä </div> <div style="text-align: center;">   Seppo Lavonen </div> </div>

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