



QUALITY SYSTEM

# CERTIFICATE

Directive 93/42/EEC

Manufacturer: Soredex  
PaloDEX Group Oy  
Nahkelantie 160  
FI-04300 Tuusula, Finland

Coverage of Certificate: Design, manufacture and final inspection

Product category: Diagnostic X-Ray Equipment and Accessories

Valid until: 5th January 2011

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-2385-01-1105-312-08-P0.

Tampere, 5th January 2008



Kaarle Kylmä



Seppo Lavonen

Certificate no.  
VTT-C-2385-01-1105-312-08




Notified Body no. 0537:  
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## DECISION

on changes to the approved quality system as specified in Annex II, Section 3 of Council Directive 93/42/EEC concerning medical devices, or to the product range covered.

Decision no.:	<b>VTT-C-2385-01-1105-312-08-P4</b>
Manufacturer:	<b>SOREDEX</b> PaloDEx Group Oy Nahkelantie 160, FI-04300 Tuusula, Finland
Date of manufacturer's notification:	6th July 2010 / Terho Turkumäki
Procedure and product category:	Design, manufacture and final inspection of diagnostic X-ray equipment and accessories
Description of the changes:	<ul style="list-style-type: none"> <li>• New product added: Dental imaging software Scanora 4.x</li> <li>• Existing product renamed due to extension of intended use: Scanora 3D</li> </ul>
The decision:	<p>The manufacturer's quality system related to the aforementioned changes has been assessed and it still meets the requirements in Annex II of Medical Device Directive 93/42/EEC. The decision is based on the Audit Report NB-1105-1106-A6 and Change Assessment Reports MR10 and MR11. The certificate covers now the following products:</p> <p>Class IIb:</p> <ul style="list-style-type: none"> <li>- Cephalometric X-ray unit, Cranex C, SL4/PT11 CO</li> <li>- Panoramic X-ray unit, Cranex Basex, Cranex Basex D, X-Mind PANO 2.5, X-Mind PANO 2.5 D, SL4/PT12</li> <li>- Panoramic X-ray unit, Cranex Excel, Cranex Excel D, X-Mind PANO, X-Mind PANO D, SL4/PT11</li> <li>- Panoramic/cephalometric X-ray unit, Cranex Excel Ceph, X-Mind PANO Ceph, SL4/PT11 C/C</li> <li>- Panoramic/cephalometric X-ray unit, Cranex F, Cranex D, Cranex D ceph, X-Mind PANO D+, X-Mind PANO ceph D+, PP1</li> <li>- Panoramic X-ray unit, Cranex Tome, X-Mind Tome, SRC1</li> <li>- Panoramic/cephalometric X-ray unit, Cranex Tome Ceph, X-Mind Tome Ceph, SRC1</li> <li>- Panoramic X-ray unit, Cranex Novus, X-Mind Novus, CRA-1</li> <li>- PT-imaging head for Scanora system, DXR 90</li> <li>- Intraoral dental X-ray unit, MINRAY, INTR</li> <li>- Dentomaxillofacial CBCT, panoramic and ENT X-ray unit, Scanora 3D, SBR3D</li> <li>- Intraoral sensor system Digora Toto, models SC-S-1-S1 and SC-S-1-S2</li> </ul>

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	<p>Class IIa:</p> <ul style="list-style-type: none"><li>- Digital imaging plate scanner, Digora PCT, DXR 80</li><li>- Digital imaging plate scanner, Digora Optime, DXR 50</li><li>- Imaging plates for DXR-40, DXR 50 and DXR 80</li><li>- Dental imaging software Scanora 3.0</li><li>- Dental imaging software Scanora 4.x</li><li>- Dental imaging software Digora for Windows 2.x (x&gt;6)</li></ul>
Certificate related to the decision:	VTT-C-2385-01-1105-312-08
Validity:	This decision is valid until 5 <sup>th</sup> January 2011 unless the validity of the related certificate is changed.
Date:	19th July 2010
	 Kaarle Kylmä  Seppo Lavonen

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**VTT EXPERT SERVICES LTD.**

Medical Device Technology

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