

QUALITY SYSTEM

---

# EC-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

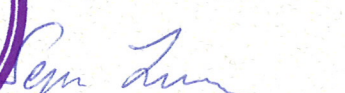
Valid until: 5th January 2016

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 attachments.

Tampere, 5<sup>th</sup> January 2011



  
Kaarle Kylmä

  
Seppo Lavonen

Certificate no.  
VTT-C-6182-01-1105-420-10

Notified Body no. 0537:  
VTT Expert Services Ltd.  
P.O. Box 345 (Tekniikankatu 1)  
FI-33101 TAMPERE  
FINLAND  
Tel.+358 20 722 111

**Attachment 4 to the Certificate number: VTT-C-6182-01-1105-420-10**

<b>Manufacturer:</b>	Soredex, PaloDEx Group Oy Nahkelantie 160, FI-04300 Tuusula Finland			
<b>Activity and product category:</b>	Design, manufacture and final inspection of Diagnostic X-Ray Equipment and Accessories			
<b>Products:</b>	The certificate covers the following products:			
	<i>Name</i>	<i>Brand name</i>	<i>Model</i>	<i>Class</i>
	Cephalometric X-Ray Unit	Soredex	Cranex C, SL4/PT11 CO	IIb
	Panoramic X-Ray unit	Soredex	Cranex Basex, Cranex Basex D, X-Mind PANO 2.5, X- Mind PANO 2.5D, SL4/PT12	IIb
	Panoramic X-Ray Unit	Soredex	Cranex Excel, Cranex Excel D, X-Mind PANO, X-Mind PANO D, SL4/PT11	IIb
	Panoramic/cephalometric X-Ray Unit	Soredex	Cranex Excel Ceph, X-Mind PANO Ceph, SL4/PT11 C/C	IIb
	Panoramic/cephalometric X-Ray Unit	Soredex	Cranex F, Cranex D, Cranex D Ceph, X-Mind PANO D+, X-Mind PANO Ceph D+, PP1	IIb
	Panoramic X-Ray unit	Soredex	Cranex Tome, X-Mind Tome, SRC1	IIb
	Panoramic/cephalometric X-Ray Unit	Soredex	Cranex Tome Ceph, X- Mind Tome Ceph, SRC1	IIb
	Panoramic X-Ray unit	Soredex	Cranex Novus, X-Mind Novus, CRA-1	IIb
	PT-Imaging Head for Scanora System	Soredex	DXR 90	IIb
	Intraoral Dental X-Ray Unit	Soredex	MINRAY, INTR	IIb
	Dentomaxillofacial CBCT,	Soredex	Scanora 3D,	IIb




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

**VTT EXPERT SERVICES LTD**

Medical Device Technology  
Tekniikankatu 1, Tampere  
P.O. BOX 345, FI-33101 TAMPERE  
FINLAND

Tel. +358 20 722 111  
Fax +358 20 722 3365

www.vtt.fi  
Business ID 2297513-2

	Panoramic and ENT X-Ray Unit		SBR3D	
	Dentomaxillofacial x-ray equipment with cephalometric and cbct options	Soredex	Cranex 3D, X-Mind 3D, PP3	IIb
	Intraoral Sensor System	Soredex	Digora Toto, SC-S-1-S1, SC-S-1-S2, SC-S-2-S2, SC-S-2-S2	IIb
	Digital Imaging Plate Scanner	Soredex	Digora PTC, DXR 80	IIa
	Digital Imaging Plate Scanner	Soredex	Digora Optime, DXR 50	IIa
	Imaging Plates	Soredex	Plates for models DXR 40, DXR 50 and DXR 80	IIa
	Dental Imaging Software	Soredex	Scanora 3.0	IIa
	Dental Imaging Software	Soredex	Scanora 4.x, 5.x (x=0-9)	IIa
	Dental Imaging Software	Soredex	Digora for Windows 2.x(x>6)	IIa
<b>Date:</b>	Tampere, 23rd September 2011			
	 Markku Helminen	 Seppo Lavonen		