

**EN EC Declaration of Conformity**

Council Directive 93/42/EEC concerning medical devices

We, manufacturer:

PaloDEX Group Oy	and	Instrumentarium Dental, PaloDEX Group Oy
Nahkelantie 160		Nahkelantie 160
FI-04300 Tuusula, Finland		FI-04300 Tuusula, Finland

certify that products described are in conformity with the applicable provisions of the Council Directive 93/42/EEC Annex II concerning medical devices.

This declaration of conformity is issued under the sole responsibility of the manufacturer.

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**GE KONFORMITÄTSEKLRÄUNG**

nach den Bestimmungen der medizinischen einrichtungen 93/42/EEC

Wir, Hersteller:

PaloDEX Group Oy	und	Instrumentarium Dental, PaloDEX Group Oy
Nahkelantie 160		Nahkelantie 160
FI-04300 Tuusula, Finland		FI-04300 Tuusula, Finland

bestätigen, dass die beschriebenen Produkte konform mit den Bestimmungen der Directive 93/42/EEC Annex II für Medizinische Einrichtungen sind.

Die alleinige Verantwortung für die Ausstellung dieser Konformitätserklärung trägt der Hersteller.

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**FR Déclaration de Conformité CE**

Directive 93/42/EEC concernant les dispositifs médicaux

Nous, fabricants:

PaloDEX Group Oy	et	Instrumentarium Dental, PaloDEX Group Oy
Nahkelantie 160		Nahkelantie 160
FI-04300 Tuusula, Finland		FI-04300 Tuusula, Finland

Certifions que les produits nommés ci-dessous sont en conformité avec les dispositions applicables de la Directive 93/42/EEC Annex II concernant les dispositifs médicaux.

La présente déclaration de conformité est établie sous la seule responsabilité du fabricant.

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**216218v.9**

**IT DICHIARAZIONE DI CONFORMITA'**

Consiglio Direttivo 93/42/EEC, riguardante i dispositivi medicali  
Noi costruttori:

PaloDEX Group Oy	e	Instrumentarium Dental, PaloDEX Group Oy
Nahkelantie 160		Nahkelantie 160
FI-04300 Tuusula, Finland		FI-04300 Tuusula, Finland

Certifichiamo che i prodotti descritti sono in conformità alle normative applicabili secondo la Direttiva 93/42/EEC Annex II riguardante i dispositivi medicali

La presente dichiarazione di conformità è rilasciata sotto la responsabilità esclusiva del fabbricante.

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**SP Declaración de Conformidad CE**

Directiva del Consejo 93/42/EEC concerniente a equipos médicos  
Nosotros, fabricantes:

PaloDEX Group Oy	y	Instrumentarium Dental, PaloDEX Group Oy
Nahkelantie 160		Nahkelantie 160
FI-04300 Tuusula, Finland		FI-04300 Tuusula, Finland

Certificamos que los productos descritos están en conformidad con las disposiciones aplicables de la Directiva del Consejo 93/42/EEC Annex II concerniente a equipos médicos.

La presente declaración de conformidad se expide bajo la exclusiva responsabilidad del fabricante.

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**Table 1.** Manufacturer / der Hersteller / le Fabricant / il Fabbricante / el Fabricante:  
PaloDEX Group Oy

<b>Description</b> <b>Beschreibung</b> <b>Description</b> <b>Descrizione</b> <b>Descripción</b>	<b>Name</b> <b>Name</b> <b>Nom</b> <b>Nome</b> <b>Nombre</b>	<b>Type</b> <b>Typ</b> <b>Type</b> <b>Type</b> <b>Tipo</b>	<b>Class</b> <b>Klasse</b> <b>Class</b> <b>Classe</b> <b>Clase</b>
CBCT, Panoramic and Cephalometric X-ray unit Panorama, Cephalometrische und CBCT Röntgeneinrichtung Système Rx de Panoramique, CBCT et céphalométrie T Apparecchio radiologico CBCT, Panoramico e cefalometrico Equipo de Rayos X Panorámico, CBCT e cefalométrico	ORTHOPANTOMOGRAPH ™ OP 3D (1)	PCX-1	II b a)
Digital imaging plate scanner Digital Speicherfolien Scanner Lecteur de plaques numériques Sistema di radiovideografia Laser digitale Escaner Digital de place de imagen	Scan eXam (2) Scan eXam One (2)	eXam5-x eXam6-x, (x=1,...)	II a a)
Imaging plates of Scan eXam/Scan eXam One Speicherfolien für Scan eXam/Scan eXam One Plaques numériques pour Scan eXam/Scan eXam One lastrine digitali per Scan eXam/Scan eXam One Placas de imágenes para Scan eXam/Scan eXam One			IIa a) b)
Protective bags Hygieneschutzhüllen Sachets de protection Protezioni di plastica Bolsas protectoras	Protective bags Hygieneschutzhüllen Sachets de protection Protezioni di plastica Bolsas protectoras		I

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**Table 2.** Manufacturer / der Hersteller / le Fabricant / il Fabbricante / el Fabricante:  
Instrumentarium Dental, PaloDEX Group Oy

<b>Description</b> <b>Beschreibung</b> <b>Description</b> <b>Descrizione</b> <b>Descripción</b>	<b>Name</b> <b>Name</b> <b>Nom</b> <b>Nome</b> <b>Nombre</b>	<b>Type</b> <b>Typ</b> <b>Type</b> <b>Type</b> <b>Tipo</b>	<b>Class</b> <b>Klasse</b> <b>Class</b> <b>Classe</b> <b>Clase</b>
CBCT, Panoramic, Cephalometric and ENT X-ray unit Panorama, Cephalometrische, CBCT und ENT Röntgeneinrichtung Système Rx de Panoramique, CBCT, céphalométrie et ENT Apparecchio radiologico CBCT, Panoramico, cefalo e ENT metrico Equipo de Rayos X Panorámico, CBCT, cefalométrico e ENT	ORTHOPANTOMOGRAPH ™ OP 3D Pro <sup>(1)</sup>	OP300, OP300-1	II b <sup>b)</sup>
Intraoral dental X-ray-device, Focus Intraoral dental X-ray-device, Focus Système de radiologie intra orale, Focus apparecchiature intraorale a raggi X, Focus Equipo de rayos X dental intraoral, Focus	Focus <sup>(3)</sup>	Focus	II b <sup>b)</sup>
Protective bags Hygieneschutzhüllen Sachets de protection Protezioni di plastica Bolsas protectoras	Protective bags Hygieneschutzhüllen Sachets de protection Protezioni di plastica Bolsas protectoras		I
Dental imaging software Dentale Bildgebungssoftware Logiciel d'imagerie dentaire Software di imaging dentale Software de imagen dental	Cliniview <sup>(4)</sup>	Cliniview 11.x	II a <sup>b)</sup>
Dental imaging software Dentale Bildgebungssoftware Logiciel d'imagerie dentaire Software di imaging dentale Software de imagen dental	Twain <sup>(4)</sup> Cliniview Mobile <sup>(4)</sup>	Twain Cliniview Mobile	I

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Conforms to/ Entspricht/ Conforme a/ Conforme/ Se ajusta a:

- 1) EN 60601-1, EN 60601-1-2, EN 60601-1-3, EN 60601-1-6, EN 62366, EN 60601-2-28, EN 60601-2-63, EN 60825-1, EN 62304
- 2) EN 60601-1, EN 60601-1-2, EN 60601-1-6, EN 62366, EN 60825-1, EN 62304
- 3) EN 60601-1, EN 60601-1-2, EN 60601-1-3, EN 60601-1-6, EN 62366, EN 60601-2-28, EN 60601-2-65, EN 62304
- 4) EN 62304

Tuusula October 20, 2020



Jari Taskinen  
Site Leader  
PaloDEX Group Oy, trading also as Instrumentarium Dental, PaloDEX Group OY

Quality System Certificates: a) C-01-1154-715-19  
b) C-01-1106-714-19

Notified Body 0537, Eurofins Expert Services

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**Appendix I. to Declaration of Conformity (MDD) signed on October 20, 2020**

The following updates have been made to the content of the DoC signed on October 20, 2020:

Quality System Certificate C-01-1154-714-19 has been removed.

The manufacturer "Instrumentarium Dental, PaloDEX Group Oy" has been removed.

Twain and Cliniview Mobile are no longer under this DoC (please see the "DoC Attachment Table 1." below).

DIGORA Optime (type DXR-60) is included under this DoC with Scan eXam and Scan eXam One (please see the "DoC Attachment Table 1." below).

"Imaging plates of Scan eXam and Scan eXam One" is simply "Imaging plates" (please see the "DoC Attachment Table 1." below).

The products no longer conform to EN 60601-2-28.

**DoC Attachment Table 1.** Manufacturer / der Hersteller / le Fabricant / il Fabbricante / el Fabricante:  
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CBCT, Panoramic and Cephalometric X-ray unit Panorama, Cephalometrische und CBCT Röntgeneinrichtung Système Rx de Panoramique, CBCT et céphalométrie T Apparechio radiologico CBCT, Panoramico e cefalometrico Equipo de Rayos X Panorámico, CBCT e cefalométrico	ORTHOPANTOMOGR APH™ OP 3D <sup>(1)</sup>	PCX-1	<b>II b</b>
Digital imaging plate scanner Digital Speicherfolien Scanner Lecteur de plaques numériques Sistema di radiovideografia Laser digitale Escaner Digital de place de imagen	Scan eXam <sup>(2)</sup> Scan eXam One <sup>(2)</sup>  DIGORA™ Optime <sup>(2)</sup>	eXam5-x eXam6-x, (x=1,...)  DXR-60	<b>II a</b>

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Imaging plates Speicherfolien Plaques numériques Lastrine digitali Placas de imágenes	N/A	N/A	II a
CBCT, Panoramic, Cephalometric and ENT X-ray unit Panorama, Cephalometrische, CBCT und ENT Röntgeneinrichtung Système Rx de Panoramique, CBCT, céphalométrie et ENT Apparecchio radiologico CBCT, Panoramico, cefalo e ENT metrico Equipo de Rayos X Panorámico, CBCT, cefalométrico e ENT	ORTHOPANTOMOGR APH™ OP 3D Pro (1)	OP300, OP300-1	II b
Intraoral dental X-ray-device, Focus Intraoral dental X-ray-device, Focus Système de radiologie intra orale, Focus apparecchiature intraorale a raggi X, Focus Equipo de rayos X dental intraoral, Focus	Focus (3)	Focus	II b
Dental imaging software Dentale Bildgebungssoftware Logiciel d'imagerie dentaire Software di imaging dentale Software de imagen dental	Cliniview (4)	Cliniview 11.x	II a

Tuusula December 4, 2024



Rainer Harjunpää  
Vice President, RA/QA – Diagnostics  
PaloDEX Group Oy

Quality System Certificate: C-01-1154-715-19

Notified Body 0537, Eurofins Expert Seviles

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