

EN EU Declaration of Conformity

We, manufacturer

PaloDEx Group Oy
Nahkelantie 160
FI-04300
Finland
SRN: FI-MF-000004943

certify that devices listed in Table 1 are in conformity with the provisions according to the regulation on medical devices, EU 2017/745 and directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment, 2011/65/EU (RoHS 2) and EU 2015/863 (RoHS 3).

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

DE EU-Konformitätserklärung

Wir, Hersteller

PaloDEx Group Oy
Nahkelantie 160
FI-04300
Finnland
SRN: FI-MF-000004943

erklären, dass die Produkte gemäß Tabelle 1 in Übereinstimmung mit den Vorschriften der Medizinprodukterichtlinie EU 2017/745 und Richtlinie zur Beschränkung der Verwendung bestimmter gefährlicher Stoffe in Elektro- und Elektronikgeräten EU 2011/65 und EU 2015/863.

Die Konformitätserklärung wurde in alleiniger Verantwortung des Herstellers ausgestellt.

FR Déclaration de conformité UE

Nous, fabricant

PaloDEx Group Oy
Nahkelantie 160
FI-04300
Finlande
SRN: FI-MF-000004943



PaloDEx Group Oy

Street address
Nahkelantie 160
04300 Tuusula
Finland

Postal address
P.O. Box 64
FI-04301 Tuusula
Finland

Phone
+358 10 270 2000

VAT
FI19774137

BI code
1977413-7

Bank
Nordea Bank
SWIFT NDEAFIHH
Account
FI9015963000046864

www.palodexgroup.com

certifions que les dispositifs énumérés dans les tableau 1 sont conformes aux dispositions du règlement relatives aux dispositifs médicaux, UE 2017/745, UE 2011/65 et UE 2015/863.

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

IT Dichiarazione di conformità UE

Noi, fabbricante

PaloDEx Group Oy
Nahkelantie 160
FI-04300
Finlandia
SRN: FI-MF-000004943

dichiariamo che le apparecchiature elencate nelle tabella 1 sono conformi alle disposizioni previste dal regolamento dispositivi medici UE 2017/745 e direttiva sulla restrizione dell'uso di determinate sostanze pericolose nelle apparecchiature elettriche ed elettroniche UE 2011/65 e UE 2015/863.

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

ES Declaración de conformidad de la UE

Nosotros, como fabricante

PaloDEx Group Oy
Nahkelantie 160
FI-04300
Finlandia
SRN: FI-MF-000004943

certificamos que los dispositivos enumerados en la Tabla 1 están en conformidad con las disposiciones según la regulación sobre dispositivos médicos UE 2017/745 y directiva sobre restricciones a la utilización de determinadas sustancias peligrosas en aparatos eléctricos y electrónicos UE 2011/65 y UE 2015/863.

Esta declaración de conformidad se emite bajo la exclusiva responsabilidad del fabricante.

Table/ Tableau/Tabla/Tavolo/Tabla 1.

Intended Purpose Zweckbestimmung Destinación Destinazione d'us Finalidad previst	Name Name Nom Nome Nombre	Model Produktmodell Le modèle Il modello Modelo	REFs	Basic UDI-DI	Risk class Risiko-klasse Classe de risque Classe di rischio Clase de riesgo	
Disposable hygiene barrier to prevent cross- contamination Einweg-Hygienebarriere zur Vermeidung von Kreuzkontaminationen Barrière sanitaire jetable pour éviter la contamination croisée Barriera sanitaria monouso per evitare la contaminazione incrociata Barrera sanitaria desechable para evitar la contaminación cruzada	Protective bags	N/A	900359-DEX	643003587HygieneSheath4N	Class I	
	Hygieneschutzhüllen	N/A	900371-DEX	0.805.3474	643003587HygieneSheath4N	Class I
	Sachets de protection	N/A	900372-DEX	0.805.3475	643003587HygieneSheath4N	Class I
	Protezioni di plastica	N/A	900374-DEX	0.805.3476	643003587HygieneSheath4N	Class I
	Bolsas protectoras	N/A	900475-DEX	0.805.0211	643003587HygieneSheath4N	Class I
		N/A	900476-DEX	0.805.0212	643003587HygieneSheath4N	Class I
		N/A	900477-DEX	0.805.0213	643003587HygieneSheath4N	Class I
		N/A	900478-DEX	0.805.0214	643003587HygieneSheath4N	Class I
		N/A	900803-DEX	0.805.3482	643003587HygieneSheath4N	Class I
		N/A	900509-DEX	0.805.0267	643003587HygieneSheath4N	Class I
		N/A	900510-DEX	0.805.0268	643003587HygieneSheath4N	Class I
		N/A	901011-DEX	0.805.4935	643003587HygieneSheath4N	Class I
		N/A	900511-DEX	0.805.0269	643003587HygieneSheath4N	Class I
		N/A	900512-DEX	0.805.0270	643003587HygieneSheath4N	Class I
		N/A	900638-DEX	0.805.1932	643003587HygieneSheath4N	Class I
		N/A	900474-DEX	0.805.0210	643003587HygieneSheath4N	Class I
		N/A	900802-DEX	0.805.3481	643003587HygieneSheath4N	Class I
		N/A	9801871-SDX	0.805.3074	643003587HygieneSheath4N	Class I
		N/A	9801872-SDX	0.805.3075	643003587HygieneSheath4N	Class I

Intended Purpose Zweckbestimmung Destination Destinazione d'us Finalidad previst	Name Name Nom Nome Nombre	Model Produktmodell Le modèle Il modello Modelo	REFs	Basic UDI-DI	Risk class Risiko-klasse Classe de risque Classe di rischio Clase de riesgo
		N/A	900183-PTU	0.805.2290	643003587HygieneSheath4N
		N/A	900184-PTU	0.805.3293	643003587HygieneSheath4N
		N/A	900185-PTU	0.805.2291	643003587HygieneSheath4N
		N/A	900186-PTU	0.805.3294	643003587HygieneSheath4N
		N/A	900670-PTU	0.805.3956	643003587HygieneSheath4N
		N/A	900671-PTU	0.805.3957	643003587HygieneSheath4N
		N/A	900672-PTU	0.805.3958	643003587HygieneSheath4N
		N/A	900673-PTU	0.805.3959	643003587HygieneSheath4N
		N/A	900606	0.805.3298	643003587HygieneSheath4N
		N/A	900320-PTU	0.805.2315	643003587HygieneSheath4N

Reference	European Standards
EN ISO 10993-1:2020	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN ISO 14971:2019+A11:2021	Medical devices - Application of risk management to medical devices
EN ISO 13485:2016+A11:2021	Medical devices - Quality management systems - Requirements for regulatory purposes
EN ISO 15223-1:2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements

Tuusula, Finland 2024-02-13



Rainer Harjunpää
VP, RA/QA - Diagnostics, PaloDEX Group Oy

Quality System Certificates PaloDEX Group Oy: EUFI29-22003740-S (ISO 13485), C-01-1154-715-19 (EC certificate), CR-03-1154-812-23 (EU certificate)

Notified Body: 0537, Eurofins Electric & Electronics Finland Oy