

16.7 Accessories for CRANEX™ Excel und BaseX

	Mat. no.	Price [€]
Accessories for CRANEX™ Excel and CRANEX™ BaseX		
Chin cup C	0.820.2039	58,-
		
Chin support	0.820.2064	
		
Chin rest holder	0.805.3116	1
CRANEX alignment spike	0.805.2938	73,-

16.8 Accessories for DIGORA™ Optime / Optime UV / Optime Classic

	Mat. no.	Price [€]
Imaging plates		
Imaging plate starter set	0.805.3926	469,-
1 size 3, 5 size 2, 2 size 1, 2 size 0		
Imaging plate i-Dot starter set	0.805.3927	
1 size 3, 5 size 2, 2 size 1, 2 size 0		
Imaging plate starter set Occlusal 4c	0.805.2317	277,-
2 x Imaging plates size 3		
50 x Protective covers size 3		
25 x Bite protector 4C		
25 x Hygiene bags 4C		
Imaging plates size 0 (22 x 31 mm), 6 pieces	0.805.3285	
Imaging plates size 1 (24 x 40 mm), 6 pieces	0.805.3286	
Imaging plates size 2 (31 x 41 mm), 6 pieces	0.805.3287	2
Imaging plates size 3 (27 x 54 mm), 6 pieces	0.805.3288	284,-
i-Dot Imaging plates size 0 (22 x 31 mm), 6 pieces	0.805.3289	7
i-Dot Imaging plates size 1 (24 x 40 mm), 6 pieces	0.805.3290	
i-Dot Imaging plates size 2 (31 x 41 mm), 6 pieces	0.805.3291	319,-

1.1.

	Mat. no.	Price [€]
i-Dot Imaging plates size 3 (27 x 54 mm), 6 pieces	0.805.3292	319,-
Protective covers, size 0, 200 pieces	0.805.3295	208,-
Protective covers, size 1, 200 pieces	0.805.3296	
Protective covers, size 2, 200 pieces	0.805.2300	
Protective covers, size 3, 200 pieces	0.805.3297	
Occlusal Accessories Set	0.805.2315	
50 x Protective covers size 3 25 x Bite protector 4C 25 x Hygiene bags 4C		
Hygiene (Optime / Optime UV)		
Starter kit hygienic protections	0.805.2227	240,-
Hygiene protection- and bite protection covers, Size 0-3, 200 pcs each		79,-
Hygiene bags size 0, 200 pcs	0.805.2290	
1.1. Hygiene bags size 1, 200 pcs	0.805.3293	
Hygiene bags size 2, 200 pcs	0.805.2291	
Hygiene bags size 3, 200 pcs	0.805.3294	
Hygiene covers, size Occlusal 4c, 100 pcs	0.805.3298	
Hygiene (Optime Classic)		
Hygiene bags Classic, size 0, 200 pieces	0.805.3956	54,-
Hygiene bags Classic, size 1, 200 pieces	0.805.3957	54,-
Hygiene bags Classic, size 2, 200 pieces	0.805.3958	
Hygiene bags Classic, size 3, 200 pieces	0.805.3959	
Accessories		
OPTI-Remover	0.805.2212	54,-
Help for remove plate at Optime Classic		54,-
Imaging plate storage box	0.805.2354	
Warranty extensions*		
DIGORA Optime Comfort - Warranty extension to 5 years*	1.010.4233	80,-
DIGORA Optime - Warranty extension to 5 years*	1.010.4234	80,-

*Warranty on all spare parts purchasable within the first 2 years.

4 Accessories introduction

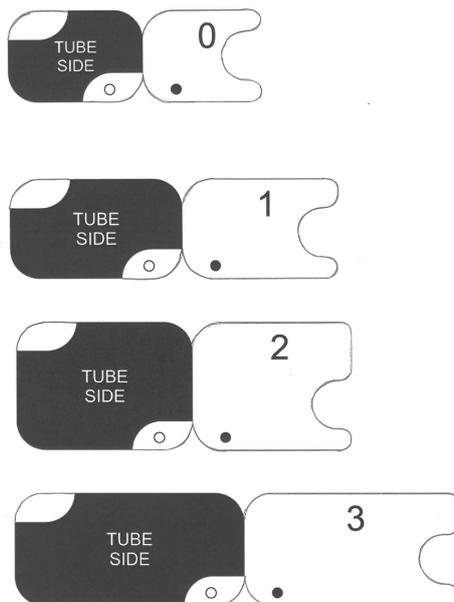
Note! USE ONLY GENUINE SOREDEX® ACCESSORIES to ensure the optimum clinical results, safe use of the system and long service life for the imaging plates.



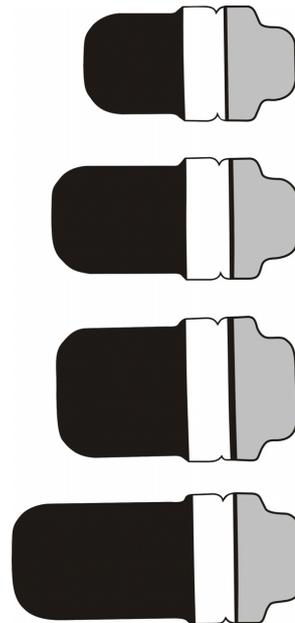
Note! Never use hygiene accessories more than once.

4.1 Hygiene accessories

Protective covers



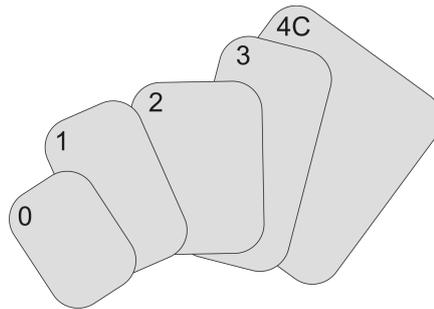
Hygiene bags 1.1.



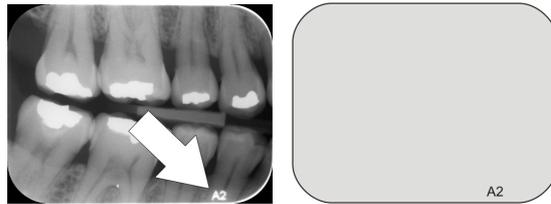
4.2 Imaging plates

Compatible with all intraoral sizes equal to film: 0, 1, 2, 3 and Comfort Occlusal™ 4C, all with film-like usability.

1.1.



IDOT™ imaging plates (optional) have individual identification marking that appear on the images.



Standard (STD) imaging plates has no identification mark on the sensitive side of the plate.



4 Priedų aprašymas

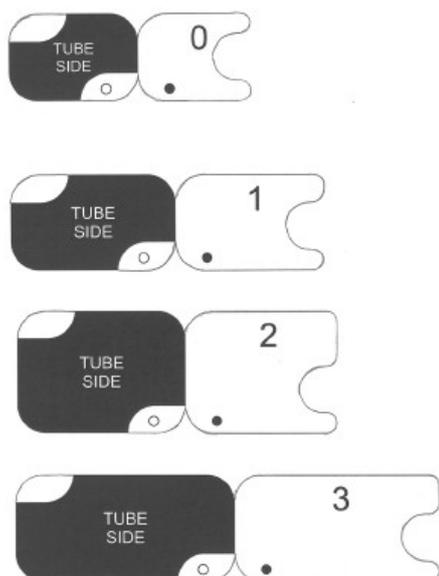
Pastaba! NAUDODAMI TIK AUTENTIŠKUS SOREDEX® PRIEDUS užtikrinsite optimalius klininius rezultatus, saugų naudojimą ir ilgą rentgenografinių plokštelių tarnavimo laiką.



Pastaba! Nenaudokite higienos reikmenų daugiau nei vieną kartą.

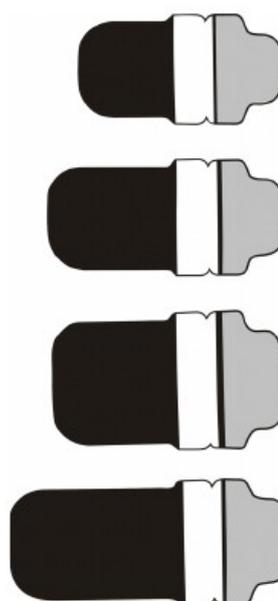
4.1 Higienos reikmenys

Apsauginiai dėkliukai



Higieniniai maišeliai

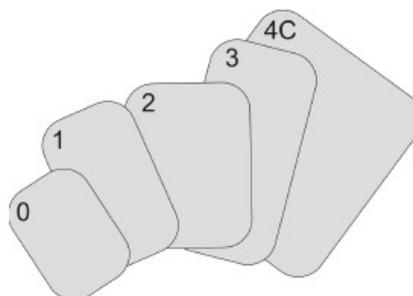
1.1.



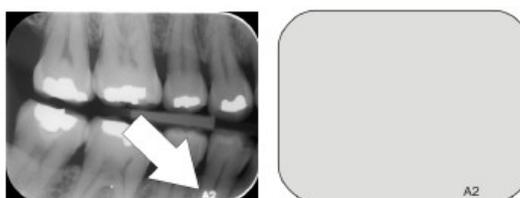
4.2 Rentgenografinės plokštelės

Atitinka visus juostelių intraoralinius dydžius: 0, 1, 2, 3 ir Comfort Occlusal™ 4C, naudojamos taip kaip ir juostelės.

1.1.

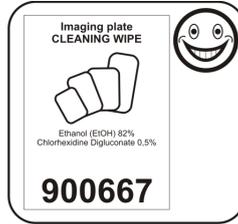


IDOT™ rentgenografinės plokštelės (užsakomos papildomai) turi identifikacijos ženklus, kurie matomi ant atvaizdų.



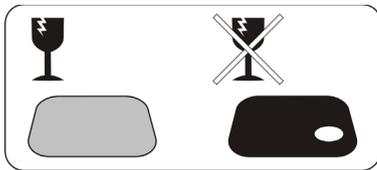
Standartinės (STD) rentgenografinės plokštelės neturi identifikacijos ženklų ant jautriosios pusės.



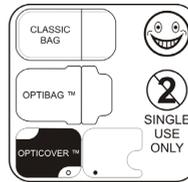


Item number 900667, box of 50 individually packed wipes.

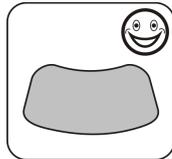
4.8 Imaging plate care



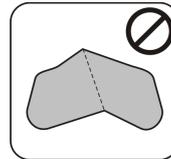
Sensitive surface, handle with care



Use only original accessories.
Single use only! 1.1.



You can bend.



Do not fold or bend excessively.



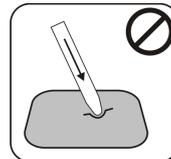
Touch the edges only.



Do not touch the sensitive surface.



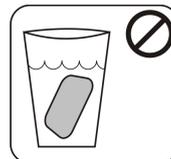
Do not scratch.



Do not stab.



Avoid moist and water.



Do not sink.

4.8 Rentgenografinių plokštelių priežiūra



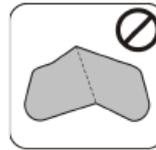
Jautrus paviršius, kurį reikia rūpestingai prižiūrėti



Naudokite tik originalius priedus.
Tik vienkartinis naudojimas! 1.1.



Galima sulenkti.



Nelankstykite arba per daug nesulenkite.



Laikykite tik už briaunų.



Nelieskite jautraus paviršiaus.



Nebraižykite.



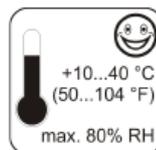
Nebadykite.



Venkite drėgmės ir vandens.



Nenardinkite į skystį.



Leistina temperatūra.



Venkite dulkių.



Venkite tiesioginių saulės spindulių ir UV spindulių.



Tai nėra buitinės atliekos.

9.4 Hygiene bag specifications

Hygiene bags	
Material	Latex-free, food-grade polyethylene
Biocompatibility conformity to standard	Not having irritative, toxic or injurious effects on biological system in accordance with ISO 10993-1 and ISO 10993-5.
Packaging	Supplied in boxes
Use	For the best performance it is recommended the hygiene bags are used within two years from the date of manufacture. The date of manufacture is printed on the bottom of the box containing the hygiene bags (DDM-MYYXX). Extended storage time or exceeding the specified storage conditions may compromise the performance of the adhesive tape and/or the plastic material from which the hygiene bags are made of.
Disposal	Observe relevant national requirements.

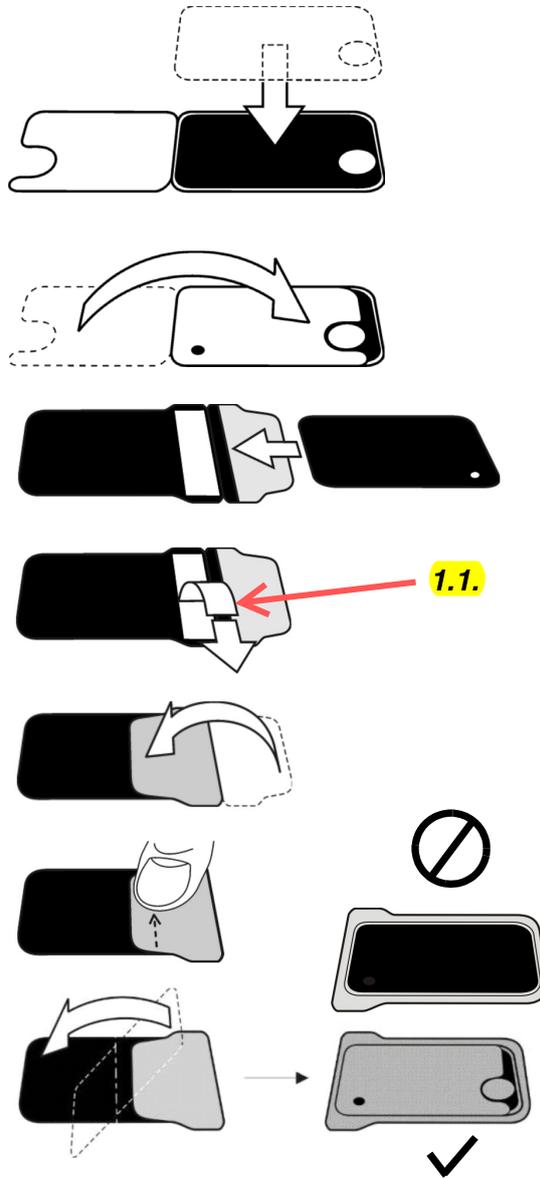
1.1.

9.4 Higieninių maišelių specifikacijos

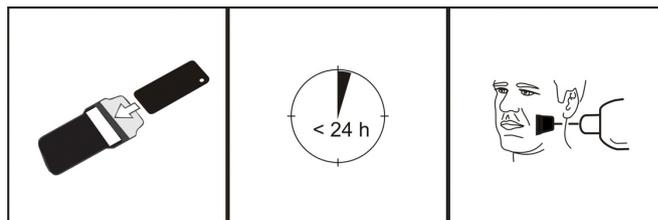
Higieniniai maišeliai	
Medžiaga	Maisto produktams skirtas polietilenas, be latekso
Biologinio suderinamumo atitikimas standartams	Biologinėms sistemoms nedaro dirginančio, toksinio ar kenksmingo poveikio pagal ISO 10993-1 ir ISO 10993-5.
Pakuotės	Pristatomi dėžutėse
Naudojimas	Siekiant užtikrinti geriausias eksploatacines savybes, higieninius maišelius rekomenduojama sunaudoti per du metus nuo pagaminimo datos. Pagaminimo data yra atspausdinta higieninių maišelių dėžutės apačioje (DD-MM-YYXX). Per ilgai laikant ar nesilaikant specialių laikymo sąlygų, gali suprastėti lipnios juostos ir / ar plastmasės, iš kurios pagaminti higieniniai maišeliai, eksploatacinės savybės.
Utilizavimas	Laikykites atitinkamų nacionalinių reikalavimų.

1.1.

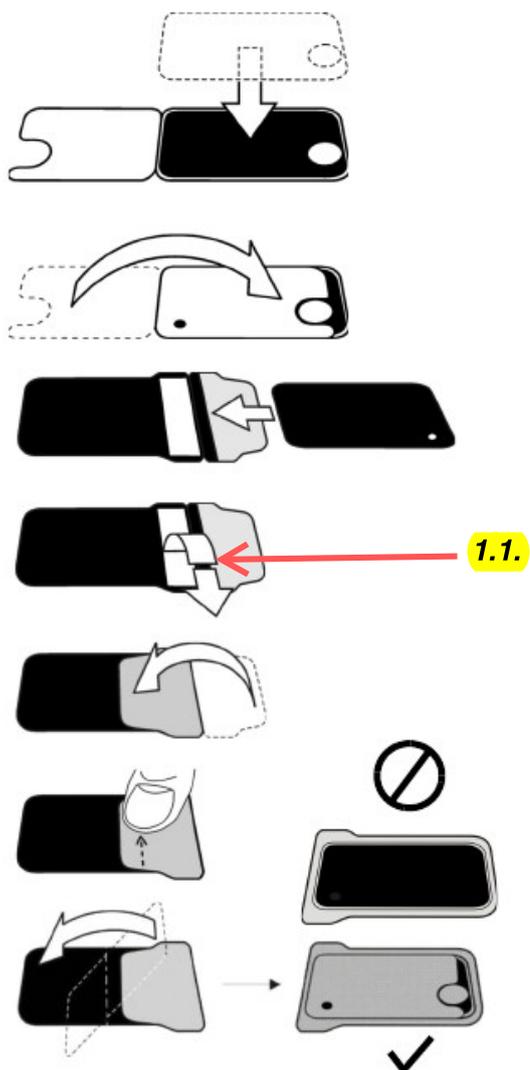
2.1 Imaging plate packing



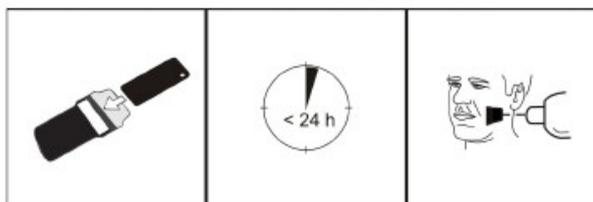
Note! Do the packing before the patient enters the reception room, but no more than 24 hours before.



2.1 Rentgenografinės plokštelės pakavimas



Pastaba! Plokštelę reikia supakuoti prieš pacientui ateinant į kabinetą, bet ne anksčiau nei prieš 24 valandas.



EN EU Declaration of Conformity

We, manufacturer

PaloDEx Group Oy
Nahkelantie 160
FI-04300
Finland

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

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.

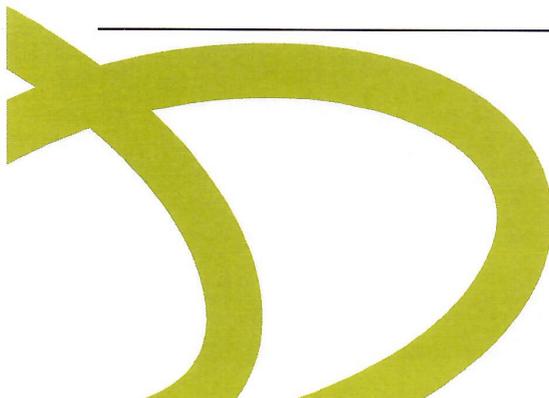
FR Déclaration de conformité UE

Nous, fabricant

PaloDEx Group Oy
Nahkelantie 160
FI-04300
Finlande

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.



PaloDEx Group Oy

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BI code
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Bank
Nordea Bank
SWIFT NDEAFIHH
Account
FI9015963000046864

IT Dichiarazione di conformità UE

Noi, fabbricante

PaloDEx Group Oy
Nahkelantie 160
FI-04300
Finlandia

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

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 1 / Tabelle 1 / Tableau 1 / Tavolo 1 / Tabla 1

Description Beschreibung Description Descrizione Descripción	Name Name Nom Nome Nombre	REF	Basic UDI-DI	Risk class Risiko-klasse Classe de risque Classe di rischio Clase de riesgo
Protective bags Hygieneschutzhüllen Sachets de protection Protezioni di plastica Bolsas protectoras	Protective bags Hygieneschutzhüllen Sachets de protection Protezioni di plastica Bolsas protectoras	203683 203685 208224 900183-PTU 900184-PTU 900185-PTU 900186-PTU 900320-PTU 900335 900359 900371 - 900374 900474 - 900478 900509 - 900512 900606 900638 900670-PTU 900671-PTU 900672-PTU 900673-PTU 900801 - 900803 901011-PTU 901140 - 901143 6801120-SDX 6801130-SDX 6801140-SDX 6801150-SDX 9801871-SDX 9801872-SDX 9802031-SDX	643003587 Hygiene Sheath4N	Class I

European Standards / Common Specifications used in the conformity assessment

EN ISO 13485:2016	Medical devices — Quality management systems — Requirements for regulatory purposes
EN ISO 14971:2019	Medical devices - Application of risk management to medical devices
EN ISO 10993-1:2020	Biological evaluation of medical devices Evaluation and testing within a risk management process

Tuusula, Finland

24.05.2021



Rainer Harjunpää
Senior Director, RA/QA – Imaging
PaloDEX Group Oy

Quality System Certificates:

PaloDEX Group Oy: C-01-1154-715-19

Notified Body:

0537, Eurofins Expert Services
Hermiankatu 6-8 H,
P.O. Box 345,
33101 Tampere, Finland

PROTECTIVE COVERS

HS Maxi Gard VL Phosphor Plate Barrier Envelopes

The light-shielding envelopes protect phosphor plates from developing due to light exposure. Suitable for all Laser-brand light-shielding envelopes. Scissors are not necessary for opening thanks to the simple opening seam. Simple closure is possible with the adhesive strips. Barrier envelopes: transparent/black.

Dimensions	Content	Barcode	Art.-no.
0	100 pieces		5701558
1	100 pieces		5701559
2	300 pieces		5701560

HS Disposable Barrier Sleeves 43 x 21 mm

HS disposable barrier sleeves for radiography for the bite plate with jaw.

Dimensions	Content	Barcode	Art.-no.
43 x 21 mm (21-mm side is open)	500 pieces		9880493



HS Disposable Barrier Sleeves 80 x 40 mm

HS disposable barrier sleeves for radiography for the bite plate and bite block.

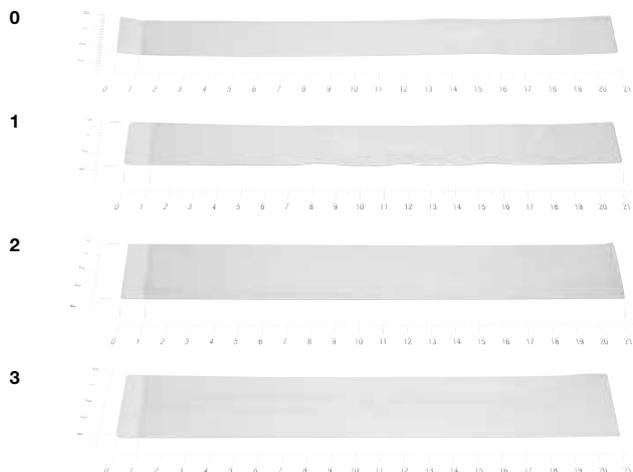
Dimensions	Content	Barcode	Art.-no.
80 x 40 mm (40-mm side is open)	500 pieces		9880494



HS Disposable Barrier Sleeves for X-ray Sensors

HS disposable barrier sleeves for x-ray sensors made from plastic (thickness 48 µ).

Dimensions	Content	Barcode	Art.-no.
0 (23 x 200 mm)	500 pieces		9880497
1 (27 x 200 mm)	500 pieces		9880498
2 (35 x 200 mm)	500 pieces		9880499 2.1.
3 (40 x 200 mm)	500 pieces		9880500



HS Disposable Barrier Sleeves 100 x 55 mm

HS disposable barrier sleeves for radiography for the bite plate with an open side.

Dimensions	Content	Barcode	Art.-no.
100 x 55 mm	500 pieces		9880495



HS Disposable Barrier Sleeves

HS disposable barrier sleeves for radiography, the forehead support, and the handle.

Dimensions	Content	Barcode	Art.-no.
210 (+140 mm) x 57 mm	500 pieces		9880496





EC Declaration of Conformity

Henry Schein, Inc. declares that the underneath described medical devices conform by design, manufacture and packaging to the Essential Requirements of the Directive 93/42/EEC concerning Medical Devices.

REF	Description
9880499	Sensor sleeves 35x200mm
9880500	Sensor sleeves 40x200mm
9880493	Disposable sleeves 43x21 mm
9880494	Disposable sleeves 80x40 mm
9880497	Sensor sleeves 23x200mm
9880498	Sensor sleeves 27x200mm

UMNDS Code: 15571, Covers

The products have been classified according to **Annex IX**, Rule 1 of the Directive:

Class I.

Conformity with the Directive has been assessed according to Annex VII.

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

Manufacturer:
Henry Schein Inc.
135 Duryea Road
Melville, NY 11747, USA

Authorized European representative:
Henry Schein UK Holdings Ltd.
Medcare House, Centurion Close
Gillingham Business Park
Gillingham, ME8 0SB U.K.

Signed for and on behalf of Henry Schein, Inc.:


Henry Schein Inc.
135 Duryea Road
Melville, NY 11747 USA
Manfred Lubberich
Director Quality and Regulatory Affairs Europe

Friday, April 12, 2019

Date