

Anexa 13 Cîntar electronic pentru nou-nascuti portabil,

Caracteristici solicitate	Caracteristici oferite 27266, Gima, Italia
Cîntar electronic, pentru nou-născuți portativ Descriere Cîntar portativ pentru nou născuți destinat pentru determinarea greutateii in conditii de deplasari la domiciliu Parametru Specificația Greutatea maximă 20 - 25 kg Precizie ≤ 5 gr Functia fixare greutate, (TARE) da Functia Auto-Hold, determinarea greutatii copilului chiar daca se misca da Husa pentru transportare da Pornirea/Închiderea Automată Ecran LCD $\geq 65 \times 25$ mm Alimentare 220V, 50Hz și baterie internă Autocalibrare da	Cîntar electronic, pentru nou-născuți portative, pliabil Descriere Cîntar portativ pentru nou născuți destinat pentru determinarea greutateii in conditii de deplasari la domiciliu Parametru Specificația Greutatea 15 kg Precizie ≤ 5 gr Functia fixare greutate, (TARE) da Functia Auto-Hold, determinarea greutatii copilului chiar daca se misca da geanta pentru transportare da(cod 27271) Pornirea/Închiderea Automată Ecran LCD $\geq 65 \times 25$ mm Alimentare : baterii , AAA Autocalibrare da



GIMA

SOEHNLE 8320 FOLDABLE BABY SCALE

Code: 27266

Category: Medical baby scales

Unit of sale: 1 pc.

Minimum order: 1

Type: No medical device



EAN13: 4006484830009

Description: Foldable baby scale for easy transport.

- Folding mechanism with magnetic lock
- Easy to open: remove the base and pull the handles apart
- Turning function: pads, blankets, placed under the baby are tarable
- Steady weight display through filtering and hold function
- Large LCD display easy to read
- Switchable to kg/lb
- Manual in: DE, GB, FR, ES, IT, GR, CZ, Arabic.

Technical Specifications:

- Capacity: 15 kg
- Sensitivity: 10 g
- Size: 395 x 315 x h 105 mm (closed) 740 x 315 x h 53 mm (open)
- Alkaline battery 2 X 1.5V AAA - not included
- Weight: 1.9 kg
- Warranty: 2 years



GIMA

CARRYING BAG for 27266

Code: 27271

Category: Medical baby scales

Unit of sale: 1 pc.

Minimum order: 1

Type: No medical device



EAN13: 4006484500568

Description: Carring bag for Soehnle 8320 foldable baby scale (code 27266).



GIMA

RI-SCOPE L2 XENON OPHTHALMOSCOPE - 3.5V

Code: 31832

Category: Riester ophthalmoscopes

Unit of sale: 1 pc.

Minimum order: 1

Type: Medical device

Class: I



EAN13: 4045396152991

Description:

The enhanced basic model with separately engageable redfree, blue and polarization filters for each aperture.

- Diopter wheel with 29 corrective lenses Plus 1-10, 12, 15, 20, 40
- Minus 1-10, 15, 20, 25, 30, 35
- Easy-to-operate aperture hand-wheel with semi-circle, small/medium/large circle, fixation star, and slit
- Includes filter wheel engageable for all apertures with symbol display, red-free filter, blue filter and polarization filter



GIMA

Li-Ion BATTERY

Code: 31841

Category: Riester otoscopes

Unit of sale: 1 pc.

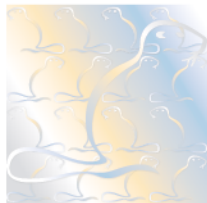
Minimum order: 1

Type: No medical device



EAN13: 4045396141506

Description: Li-ion batteries - greatest power in the smallest space!
Considerably higher charging capacity, longer lifetime, lightweight, these are the big advantages of Li-ions batteries; wich provide sustained high performance for up to 1200 charging cycles. LEDs powered by lithium batteries can burn for up to 50 hours.



Reg. Number	10164 - M	Valid From	2018-10-01
First issue date	2012-10-15	Last change date	2020-05-06
Valid until	2021-10-14		

Previous expiry date

Quality Management System Certificate

ISO 13485:2016

We certify that the Quality Management System of the Organization:

GIMA S.p.A.

Is in compliance with the standard UNI CEI EN ISO 13485:2016 for the following products/services:

Management of design and manufacturing, trade, packaging and assistance of: medical devices (DM), in vitro-diagnostic medical devices (IVD), accessories

Chief Operating Officer
Giampiero Belcredi

The maintaining of certification is subject to annual surveillance and dependent upon the observance of Kiwa Cermet Italia contractual requirements.

Refer to quality manual for details of exclusion of UNI CEI EN ISO 13485:2016 requirements.

This certificate is composed of 1 page.

Kiwa Cermet Italia S.p.A.
Società con socio unico,
soggetta all'attività di
direzione e coordinamento di
Kiwa Italia Holding Srl

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CERMET

GIMA S.p.A.

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Certified Sites

- Via Marconi, 1 20060 Gessate (MI) Italia



Nr. KE-551	KONFORMITÄTSERKLÄRUNG DECLARATION OF CONFORMITY DECLARACIÓN DE CONFORMIDAD Nach Anhang VII According to Annex VII Según Anexo VII	
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Rudolf Riester GmbH
Bruckstraße 31, D-72417 Jungingen, Germany
Tel.: (+49) (0)7477-9270-0
Fax: (+49) (0)7477-9270-70
E-mail: info@riester.de
www.riester.de

Wir erklären in alleiniger Verantwortung, dass das Medizinprodukt
 We declare under our sole responsibility that the medical device
 Declaramos bajo nuestra responsabilidad que el producto médico

ri-scope® L ophthalmoscope L2 XL 3.5 V, C handle for ri-accu®L

Artikel-Nr. von: / Article no. from: / **3725-550**
 Desde no. de artículo:

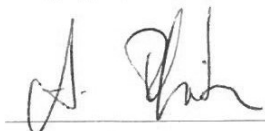
Artikel-Nr. bis: / Article no. to / **3725-550**
 Al no. de artículo:

allen Anforderungen der Medizinprodukte-Richtlinie 93/42/EWG entspricht, die anwendbar sind.
 meets all the provisions of the directive 93/42/EEC which apply to it.
 cumple con todas las exigencias de la directiva 93/42/CEE a los cuales se refiere.

Richtlinien-Klassifizierung nach Anhang IX:	Klasse I
Directive classification according to annex IX:	Class I
Clasificación de la directiva según anexo IX:	Clase I

Diese Konformitätserklärung ist gültig bis: **25.05.2021**
 This declaration of conformity is valid until:
 Esta declaración de conformidad es válida hasta:

Jungingen, 29.05.2020



Leiter Qualitätsmanagement
 Quality Manager
 Directivo de calidad



DECLARATION OF CONFORMITY

We declare under own responsibility that the following products:

6163, 7810, 8310, 8320, 8352, 9202, 9203, 6808, 6831, 6958, 5003, 5005.11, 5002.01, 5002.02

manufactured by us meet the provisions of Metrological aspects of non-automatic weighing instruments

EN 45501

In general we meet the following directives:

Directive / Standard	
Company standard scale	FR 001
EMV directive	2014/30/EU
immunity criterion	A (3V/m)
ESD criterion	B
burst criterion	(B)
Surge criterion	(B)
Low voltage directive	2014/35/EU
Battery directive	2006/66/EC
REACH	(EG) No. 1907/2006
Protection class	EN 60 529
RoHS	2011/65/EU

Validity:
valid from 01.01.2020

Soehnle Industrial Solutions GmbH
Gaildorfer Str. 6
71522 Backnang, Germany



Günter Kollat
General Manager



GIMA

RI-CHARGER L - 230V

Code: 31840

Category: Riester otoscopes

Unit of sale: 1 pc.

Minimum order: 1

Type: Medical device

Class: I

NSIS: 872314

CND: R9099

EAN13: 4045396141520

Description: Table recharge station (with wall holder) recharge 2 "C" handles with Li-Ion batteries.



Anexa 14 Oftalmoscop direct

Caracteristici solicitate	Caracteristici oferite 31382/Ri-Scope, Gima/Rudolf Riester
OFTALMOSCOPI DIRECT I. Cap oftalmoscop: Materialul capului – metal; Optica – lentile asferice (aspherical optical system); Valorile lentilelor : +dpt 1-10 (pas de 1 dpt), pînă la 35- 40 -dpt 1-10 (pas de 1 dpt), pînă la 35-40 Afişarea valorilor dioptrice – plus – verde, minus – roşu; Diafragme – 6-7 (diafragme mică, medie, maculă, fantă, semidisc, stea de fixaţie); Filtre de interferenţă fără roşu (red-free); Sursa de lumină – bec Xenon halogen, 3,5V/ 2,5V, lumină albă; Ocular multistrat, cu protecţie antipraf; Suport moale stabilizator pentru sprînceană. II. Mîner-acumulator: Formă – cilindrică, ergonomică; Baterie reîncărcabilă – NiMH sau Li-ion; III. Transformator: Priza – europeană; Curentul input –240 V AC, 50-60 Hz, Clasa de protecţie – II. IV. General Cutie depozitare - da; Lampă de rezervă – 1 buc.;	OFTALMOSCOPI DIRECT I. Cap oftalmoscop: Materialul capului – metal+ plastic; Optica – lentile asferice (aspherical optical system); Valorile lentilelor : +dpt 1-10 (pas de 1 dpt), pînă la 40 -dpt 1-10 (pas de 1 dpt), pînă la 35 Afişarea valorilor dioptrice – plus – verde, minus – roşu; Diafragme – 6-7 (diafragme mică, medie, maculă, fantă, semidisc, stea de fixaţie); Filtre de interferenţă fără roşu (red-free), albastru si polarizat; Sursa de lumină – bec Xenon halogen, 3,5V, lumină albă; Ocular multistrat, cu protecţie antipraf; Suport moale stabilizator pentru sprînceană. II. Mîner-acumulator: Formă – cilindrică, ergonomică; Baterie reîncărcabilă –Li-ion; III. Transformator: Priza – europeană; Curentul input –240 V AC, 50-60 Hz, Clasa de protecţie – II. IV. General Cutie depozitare - da; Lampă de rezervă – 1 buc.;