



EU DECLARATION OF CONFORMITY

HEINE Optotechnik GmbH & Co. KG
Dornierstr. 6, 82205 Gilching, Germany
www.heine.com

Single Registration Number: DE-MF-000006269

OTOSCOPES

We hereby declare, under sole responsibility, that the devices covered by the present EU declaration of conformity are in accordance with the MDR 2017/745.

The otoscopes consist of following combinations of

Product name	Basic UDI-DI	GMDN	UMDNS
BETA 200 LED	4053755_O_01_ZQ	12849	12-849
BETA 200			
BETA 400 LED			
BETA 400			
K180			
mini3000			
mini3000 F.O. LED			
mini3000 F.O.			
G100 LED			
G100			

and

mini3000 battery handle	4053755_BH_01_YN	--	16-337
BETA battery handle			
BETA SLIM battery handle			
Large battery handle			
BETA 4 USB rechargeable handle	4053755_RH_01_79		
BETA 4 NT rechargeable handle			
BETA 4 SLIM NT rechargeable handle			
BETA NT rechargeable handle			
BETA L rechargeable handle			
BETA SLIM NT rechargeable handle			
mini3000 rechargeable handle			
EN 200 wall transformer	4053755_WT_01_DE	16933	16-935
EN 200-1 wall transformer			

The otoscopes are class I according to the risk classification of Annex VIII.




References to any common specifications: N/A

This declaration of conformity is valid until a revised declaration of conformity is issued.

HEINE OPTOTECHNIK
GmbH & Co. KG
Dornierstr. 6
82205 Gilching

Gilching, 20 January 2022
(Place and date of issue)


Thomas Sauerer / PRRC
(Name/function and signature)



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ACCESSORIES

We hereby declare, under sole responsibility, that the following accessories lists covered by the present EU declaration of conformity are in accordance with the MDR 2017/745.

For hand-held slit lamp

Product name	Basic UDI-DI	GMDN	UMDNS
Loupe attachment for HSL 10x	4053755_HHS-A_01_2K	--	--

For headlights

Product name	Basic UDI-DI	GMDN	UMDNS
Yellow filter for Loupelights/MicroLights	4053755_H-A_01_TU	--	--
Yellow filter for ML4 LED			
Polarisation filter P2 for Loupelights/MicroLi	4053755_H-A_02_TX		
Polarisation filter P2 for ML4 LED			

For indirect ophthalmoscopes

Product name	Basic UDI-DI	GMDN	UMDNS
A.R. 16D Ophthalmoscopy lenses	4053755_IO-A_01_CS	--	--
A.R. 20D Ophthalmoscopy lenses			
A.R. 30D Ophthalmoscopy lenses			

For binocular loupes

OF binocular Loupes			
Product name	Basic UDI-DI	GMDN	UMDNS
Sterilisable Swivel Levers	4053755_BL-A_01_72	--	--
Sterilisable Swivel Levers			
HR Close-up Lenses	4053755_BL-A_02_75		
Protective Lenses for HR Loupes			
Protective Lenses for HRP Loupes			
Protective Lenses for C 2.3			
Protective Lenses C 2.3 K.			
Clip-in correction frame	4053755_BL-A_03_78		
Polarisation filter P2 for HR Loupes			

For otoscopes

Product name	Basic UDI-DI	GMDN	UMDNS
Tip-Adaptor	4053755_O-A_01_XK	--	--
Reusable Tips SANALON S		33395	13-662
Reusable Specula SANALON S			
Closed Specula SANALON S			



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Product name	Basic UDI-DI	GMDN	UMDNS
Disposable Tips AllSpec	4053755_O-A_02_XN	34897	
Disposable Specula UniSpec			
Soft Disposable Tips			
Insufflation Bulb	4053755_O-A_03_XR	--	16-448

For pocket lights

Product name	Basic UDI-DI	GMDN	UMDNS
Ear Light	4053755_PL-A_01_FC	36843	12-276
Disposable plastic tongue-blades	4053755_TD-A_01_DG	42461	--

For proctological instruments

Product name	Basic UDI-DI	GMDN	UMDNS
Double Insufflation Bulb	4053755_PI-A_02_DU	35800	16-448
Hygiene Filter	4053755_PI-A_03_DX	--	11-712

For sphygmomanometer

Product name	Basic UDI-DI	GMDN	UMDNS
Cuff GAMMA G7/G5/GP Infant, child, adult adult, adult large, thigh	4053755_AS-A_01_A6	34978	--
Cuff GAMMA XXL LF Infant, child, adult sm adult, adult large, thigh			

For tongue depressors

Product name	Basic UDI-DI	GMDN	UMDNS
Disposable plastic tongue-blade	4053755_TD-A_01_DG	42461	--


The accessories are class I according to the risk classification of Annex VIII.



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