



EU DECLARATION OF CONFORMITY

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

Single Registration Number: DE-MF-000006269

HEINE 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.

Accessory for hand-held slit lamp

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

Accessories 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/MicroLights	4053755_H-A_02_TX		
Polarisation filter P2 for ML4 LED			

Accessories 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			

Accessories for 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			
Polarisation filter P2 for HR Loupes	4053755_BL-A_03_78		
Polarisation filter P2 for HRP Loupes			

**Accessories for otoscopes**

Product name	Basic UDI-DI	GMDN	UMDNS	
Tip-Adaptor	4053755_O-A_01_XK	46114	--	
Reusable Tips SANALON S		33395	13-662	
Reusable Specula SANALON S				
Closed Specula SANALON S				
Disposable Tips AllSpec	4053755_O-A_02_XN	34897		
Disposable Specula UniSpec				
Soft Disposable Tips				
Insufflation Bulb	4053755_O-A_03_XR	--	16-448	

Accessories 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	--

Accessories 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

Accessories for sphygmomanometer

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

Accessory for tongue depressors

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

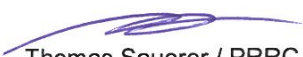
The accessories are class I according to the risk classification of Annex VIII.



References to any common specifications: N/A

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

Gilching, 10 June 2021
(Place and date of issue)


Thomas Sauerer / PRRC
(Name/function and signature)

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