



EU DECLARATION OF CONFORMITY

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

Single Registration Number: DE-MF-000006269

HEINE Proctological Instruments

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 proctological instrument consists of following combinations of

Product name	Basic UDI-DI	GMDN	UMDNS
Instrument Head for HEINE UniSpec Tubes	4053755_PI_01_6S	--	--

and

Product name	Basic UDI-DI	GMDN	UMDNS
BETA battery handle	405355_BH_01_YN		
BETA SLIM battery handle			
Large battery handle			
BETA 4 USB rechargeable handle	4053755_RH_01_79	--	16-337
BETA 4 NT rechargeable handle			
BETA 4 SLIM NT rechargeable handle			
BETA NT rechargeable handle			
BETA L rechargeable handle			
BETA SLIM NT rechargeable handle			
EN 200 wall transformer	4053755_WT_01_DE	16933	16-935
EN 200-1 wall transformer			

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


Thomas Sauerer / PRRC
(Name/function and signature)