



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 | -- | 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 | | | |
| mini3000 rechargeable handle | 4053755_WT_01_DE | 16933 | 16-935 |
| EN 200 wall transformer | | | |
| 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)