



# EU DECLARATION OF CONFORMITY

**HEINE Optotechnik GmbH & Co. KG**  
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Single Registration Number: DE-MF-000006269

## OPHTHALMIC LAMPS

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 ophthalmic lamps consist of following combinations of

| Product name                | Basic UDI-DI     | GMDN | UMDNS  |
|-----------------------------|------------------|------|--------|
| Ophthalmic Examination Lamp | 4053755_OL_01_7E | --   | 15-228 |
| Finoff Transilluminator     | 4053755_OL_02_7H | --   | 15-228 |

and

|                                    |                  |       |        |
|------------------------------------|------------------|-------|--------|
| BETA battery handle                | 4053755_BH_01_YN | --    | 16-337 |
| 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   | 4053755_WT_01_DE | 16933 | 16-935 |
| EN 200 wall transformer            |                  |       |        |
| EN 200-1 wall transformer          |                  |       |        |

The ophthalmic lamps 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**  
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Gilching, 22 March 2022  
(Place and date of issue)

  
Thomas Sauerer / PRRC  
(Name/function and signature)