



## EU DECLARATION OF CONFORMITY

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

### 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

| 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.



References to any common specifications: N/A

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

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

  
Thomas Sauerer / PRRC  
(Name/function and signature)

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