



Statement concerning the placing on the market of systems

HEINE Optotechnik GmbH & Co. KG
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Single Registration Number: DE-PR-000035500

Product family: **Otoscopes**
System: **MINI3000 OTO.+HANDLE+TIPS**

This statement describes the information required for the following systems in accordance with article 22 of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 05 April 2017 concerning medical devices.

The systems

| Article number | System description | Basic UDI-DI | GMDN | UMDNS |
|----------------|--------------------------------------|-------------------|-------|--------|
| D-008.70.120 | MINI3000 LED F.O.OTO.+HAN+TIPS | 4053755_O-S_15_6D | 45085 | 15-895 |
| D-008.70.220 | MINI 3000 LED OTOSC.HANDLE + TIPS | | | |

consist of

| Product name | Product group | Basic UDI-DI | GMDN | UMDNS |
|---------------|-----------------|-------------------|-------|--------|
| mini 3000 LED | Otoscopes | 4053755_O_03_ZW | 12849 | 12-849 |
| and | | | | |
| mini3000 | Battery handle | 4053755_BH_01_YN | -- | 16-337 |
| and | | | | |
| AllSpec | Disposable tips | 4053755_O-A_02_XN | 34897 | 13-662 |
| SANALON S | Reusable tips | 4053755_O-A_01_XK | 33395 | 13-662 |

We, HEINE Optotechnik GmbH & Co. KG, hereby declare, that the devices of the systems, covered by this statement, are compatible with each other when they are put into operation in accordance with the instruction for use.

The devices of the systems are packaged by HEINE Optotechnik GmbH & Co. KG and the relevant user instructions are given. All necessary information on the respective devices supplied by the manufacturer has been taken into account.

The activity of combining the devices as systems is subjected to appropriated methods of internal monitoring, verification and validation.

This statement is valid until a revised version is issued.

Gilching, 8 October 2024
(Place and date of issue)

Thomas Sauerer / PRRC
(Name/function and signature)

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