

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: **Otoscopies**
System: **MINI3000 OTO+HAN+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-008.70.110	MINI3000 LED F.O.OTO+HAN+XTIPS	4053755_O-S_14_6A	45085	15-895
D-008.70.210	MINI 3000 LED OTO.+HANDLE+1 X TIPS			

consist of

Product name	Product group	Basic UDI-DI	GMDN	UMDNS
mini 3000 LED	Otoscope	4053755_O_03_ZW	12849	12-849

and

mini3000	Battery handle	4053755_BH_01_YN	--	16-337
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and

AllSpec	Disposable tips	4053755_O-A_02_XN	34897	13-662
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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.

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


Thomas Sauerer / PRRC
(Name/function and signature)