

Statement concerning the placing on the market of systems



HEINE Optotechnik GmbH & Co. KG
Dornierstr. 6, 82205 Gilching, Germany
www.heine.com

Single Registration Number: DE-PR-000035500

Product family: Direct ophthalmoscopes
System: MINI3000 OPTH.W. BATT.HANDLE

This statement describes the information required for the following system 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 system

Article number	System description	Basic UDI-DI	GMDN	UMDNS
D-008.71.120	MINI3000 LED OPHTH.W.BATT.HAN.	4053755_DO-S_10_G3	45084	15-895

consists of

Product name	Product group	Basic UDI-DI	GMDN	UMDNS
mini 3000 LED	Direct ophthalmoscope	4053755_DO_03_46	46786	12-817

and

mini3000	Battery handle	4053755_BH_01_YN	--	16-337
----------	----------------	------------------	----	--------

We, HEINE Optotechnik GmbH & Co. KG, hereby declare, that the devices of the system, 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 system 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 system is subjected to appropriated methods of internal monitoring, verification and validation.

This statement is valid until a revised version is issued.

Gilching, 16 October 2024
(Place and date of issue)

Thomas Sauerer / PRRC
(Name/function and signature)

HEINE OPTOTECHNIK
GmbH & Co. KG
Dornierstr. 6
82205 Gilching