

Statement concerning the placing on the market of systems



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Single Registration Number: DE-PR-000035500

Product family: Dermatocopes
System: MINI3000 DERM.+CONT.PL.+HANDLE

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

The systems

Article number	Article description	Basic UDI-DI	GMDN	UMDNS
D-008.78.107	MINI3000 LED DERM.+CONT+HA	4053755_D-S_13_Y9	60353	15-895
D-008.78.109	MINI3000 LED DERM.+CONT+HA			

consist of

Product name	Product group	Basic UDI-DI	GMDN	UMDNS
mini3000 LED	Dermatoscope	4053755_D_04_W8	18021	18-021

and

mini3000	Battery handle	4053755_BH_01_YN	--	16-337
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and

mini3000 LED	Contact plates	4053755_D-A_03_RW	--	--
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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 methos 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)

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