

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: **Otosopes**
System: **MINI3000 OTO+TIPS SET**

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-885.20.021	MINI3000 LED F.O.OTO+TIPS SET	4053755_O-S_17_6K	45085	15-895
D-856.20.021	MINI 3000 LED OTOSC. SET			

consist of

Product name	Product group	Basic UDI-DI	GMDN	UMDNS
mini 3000 LED	Otosopes	4053755_O_03_ZW	12849	12-849
mini 3000 F.O. LED				

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

and

HARD CASE FOR MINI SET	Case	--	--	--
---------------------------	------	----	----	----

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
GmbH & Co. KG
Dornierstr. 6
82205 Gilching

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

Thomas Sauerer / PRRC
(Name/function and signature)