



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: Examination sets
System: K180 OPH./OTO. SET+BETA

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
A-279.10.118	K180 LED OPH./OTO. SET+BETA	4053755_E-S_23_YX	45084	15-895

consist of

Product name	Product group	Basic UDI-DI	GMDN	UMDNS
K180 LED	Otoscope	4053755_O_02_ZT	12849	12-849

and

K180 LED	Direct Ophthalmoscope	4053755_DO_02_43	46786	12-817
----------	-----------------------	------------------	-------	--------

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	Case	--	--	--
-----------	------	----	----	----

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.

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

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

Timo Martin / CEO
(Name/function and signature)