EU DECLARATION OF CONFORMITY

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

Single Registration Number: DE-MF-000006269

Medical device

Product family: **Direct ophthalmoscopes**
Product group: K180

We hereby declare, under our sole responsibility, the conformity of the following product in accordance with the Regulation (EU) 2017/745 of the European Parliament and of the Council of 05 April 2017 concerning medical devices.

The direct ophthalmoscope

Product name	K180

Basic UDI-DI	4053755_DO_02_43
GMDN	46786
UMDNS	12-817
EMDN	Z12120114
Classification	Class I according annex VIII

with the associated power sources as part of the medical device

Battery handles	BETA	BETA SLIM	Large
Rechargeable handles	BETA NT	BETA SLIM NT	BETA 4 USB
	BETA L	BETA 4SLIM NT	BETA 4 NT
Wall transformer	EN 200	EN 200-1	

is a medical device of class I.

CE

HEINE Optotechnik GmbH & Co. KG hereby declares that the product covered by this declaration is in conformity with this Regulation and, where applicable, with other relevant EU legislation providing for the issuing of an EU declaration of conformity.

References to any common specifications: None

Conformity assessment procedure chosen: Technical documentation according Annexes II and III

This declaration of conformity is valid until a revised declaration of conformity is issued.

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

Gilching, 09 August 2023
(Place and date of issue)

Thomas Sauerer / PRRC
(Name/function and signature)