



EU DECLARATION OF CONFORMITY

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

Single Registration Number: DE-MF-000006269

Accessory

Product family: Proctological instruments
Product group: UniSpec disposable tubes

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

Product name	UniSpec disposable tubes anoscope	UniSpec disposable tubes proctoscope	UniSpec disposable tubes sigmoidoscope
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Basic UDI-DI	4053755_PI-A_01_DR
GMDN	--
UMDNS	--
EMDN	Z12020699
Classification	Class I according annex VIII



HEINE Optotechnik GmbH & Co. KG hereby declares that the products covered by this declaration are 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, 30 April 2024
(Place and date of issue)


Thomas Sauerer / PRRC
(Name/function and signature)