



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	44914	40502	63880
UMDNS	--		
EMDN	Z12020699		
Classification	Class I according to 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 to Annexes II and III

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

Gilching, 18 November 2025
(Place and date of issue)


Thomas Sauerer / PRRC
(Name/function and signature)

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