



EU DECLARATION OF CONFORMITY

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

Single Registration Number: DE-MF-000006269

HEINE Laryngoscopes

We hereby declare, under sole responsibility, that the devices covered by the present EU declaration of conformity are in accordance with the MDR 2017/745.

The laryngoscopes consist of following combinations of

Product name	Basic UDI-DI	GMDN	UMDNS
Classic+ Macintosh reusable blade	4053755_RLB_01_DS	46827	15-076
Classic+ Miller reusable blade			
Classic+ WIS reusable blade			
Classic+ Paed reusable blade			
FlexTip+ Macintosh reusable blade			
XP Macintosh disposable blade	4053755_DLB_01_6C	46828	15-076
XP Miller disposable blade			

and

Product name	Basic UDI-DI	GMDN	UMDNS
EasyClean LED reusable handle	4053755_RLH_01_FU	46830	15-076
EasyClean LED SHORT reusable handle			
EasyClean LED SLIM reusable handle			
STANDARD F.O. 4 LED NT reusable handle			
STANDARD F.O. 4 NT reusable handle			
STANDARD F.O. LED reusable handle			
STANDARD F.O. reusable handle			
F.O. 4 SLIM LED NT reusable handle			
F.O. 4 SLIM NT reusable handle			
F.O. SLIM LED reusable handle			
F.O. SLIM reusable handle			
F.O. 4 SHORT LED NT reusable handle			
F.O. 4 SHORT NT reusable handle			
SMALL F.O. LED reusable handle			
SMALL F.O. reusable handle			
SHORT F.O. LED reusable handle			
SHORT F.O. reusable handle			
XP disposable handle			




The laryngoscopes are class I according to the risk classification of Annex VIII.



References to any common specifications: N/A

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

Gilching, 10 June 2021
(Place and date of issue)


Thomas Sauerer / PRRC
(Name/function and signature)

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