

## **EU DECLARATION OF CONFORMITY**

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

www.heine.com

Single Registration Number: DE-MF-000006269

## **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			
EasyClean LED reusable handle			
FasyClean LFD SHORT reusable handle			

FaceOlana I FD acception bondle			
EasyClean LED reusable handle			
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	4053755_RLH_01_FU	46830	15-076
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	4053755_DLH_01_8E	47806	



## **EU DECLARATION OF CONFORMITY**

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.

HEINE OPTOTEGANIA GmbH & Co. KG

Thomas Sauerer / PRRC (Name/function and signature)

Dornierstr. 6 82205 Gilching

Gilching, 20 January 2022 (Place and date of issue)