



## EU DECLARATION OF CONFORMITY

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

Single Registration Number: DE-MF-000006269

### HEINE Tongue Depressor

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 tongue depressors consist of following combinations of

Product name	Basic UDI-DI	GMDN	UMDNS
Tongue blade holder	4053755_TD_01_6P	63659	14-066
Tongue blade holder disposable blade			
Tongue blade holder mini3000			

and

Product name	Basic UDI-DI	GMDN	UMDNS
mini3000 battery handle	405355_BH_01_YN	--	16-337
BETA battery handle			
BETA SLIM battery handle			
Large battery handle			
BETA 4 USB rechargeable handle	4053755_RH_01_79	--	16-337
BETA 4 NT rechargeable handle			
BETA 4 SLIM NT rechargeable handle			
BETA NT rechargeable handle			
BETA L rechargeable handle			
BETA SLIM NT rechargeable handle			
mini3000 rechargeable handle	4053755_WT_01_DE	16933	16-935
EN 200 wall transformer			
EN 200-1 wall transformer			

HEINE Doc: Implantationssysteme MDR 20210017




The tongue depressors 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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