

# EU- MDR 2017/745 Declaration of Conformity

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Product group:	Revision Status:	
TD 001 Human Syringes class I	2.0	

We, the HENKE-SASS, WOLF GmbH, declare in our own responsibility that the following products are in compliance with the general safety- and performance requirements according to the regulation (EU) 2017/745, Annex I and are therefore in conformity with regulation (EU) 2017/745.

**Manufacturers Name Address** 

HENKE-SASS, WOLF GmbH

Keltenstraße 1, 78532 Tuttlingen

Germany

SRN (Single Registration Number)

DE-MF-000005531

# **Products/ Product Groups**

Product Group	Basic UDI-DI	Risk Class	Rule
HSW ULTRA-JANET 50 ml/100 ml/150 ml/200 ml	4035873100102TR	I	2
HSW UNIVERSAL-Ohrenspritze 10 ml	4035873100103TT	I	2
HSW SCHIMMELBUSCH 50 ml/75 ml/125 ml	4035873100102TR	I	2

#### Intended Use:

#### **HSW ULTRA-JANET**

Reusable glass/metal wound and bladder syringe (with attachments) for medical irrigation and flushing in human applications.

#### **HSW UNIVERSAL-Ohrenspritze**

The medical product is used for the gentle and thorough removal of wax or deposits from the ear.

#### **HSW SCHIMMELBUSCH**

Reusable metal ear and irrigation syringe (with attachments and protective disk available as optional accessories) for medical irrigation and flushing in human applications.

# This Declaration of Conformity is valid until

13th of December 2028

### Reference to list of applied standards

Attachment\_4-1\_GENERAL SAFETY AND PERFORMANCE REQUIREMENTS

### The Conformity assessment according to

Regulation (EU) 2017/745 (MDR) on Medical Devices, Article 52 (7), Article 19 and Technical Documentation

according to Annex II and III.

Tuttlingen, 19.02.2025

Place and Date of issue

i.V. Andreas Mantay

Senior Director Global Quality &

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**Company Stamp**