

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 776601 R000

Manufacturer: Henke-Sass, Wolf GmbH

Address:

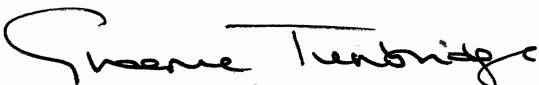
Keltenstrasse 1
78532 Tuttlingen
Germany

Single Registration Number: DE-MF-000005531

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):



Graeme Tunbridge, Senior Vice President Medical Devices

First Issue Date: **2023-12-14**

Current Issue Date: **2023-12-14**

Starting Validity Date: **2023-12-14**

Expiry Date: **2028-12-13**

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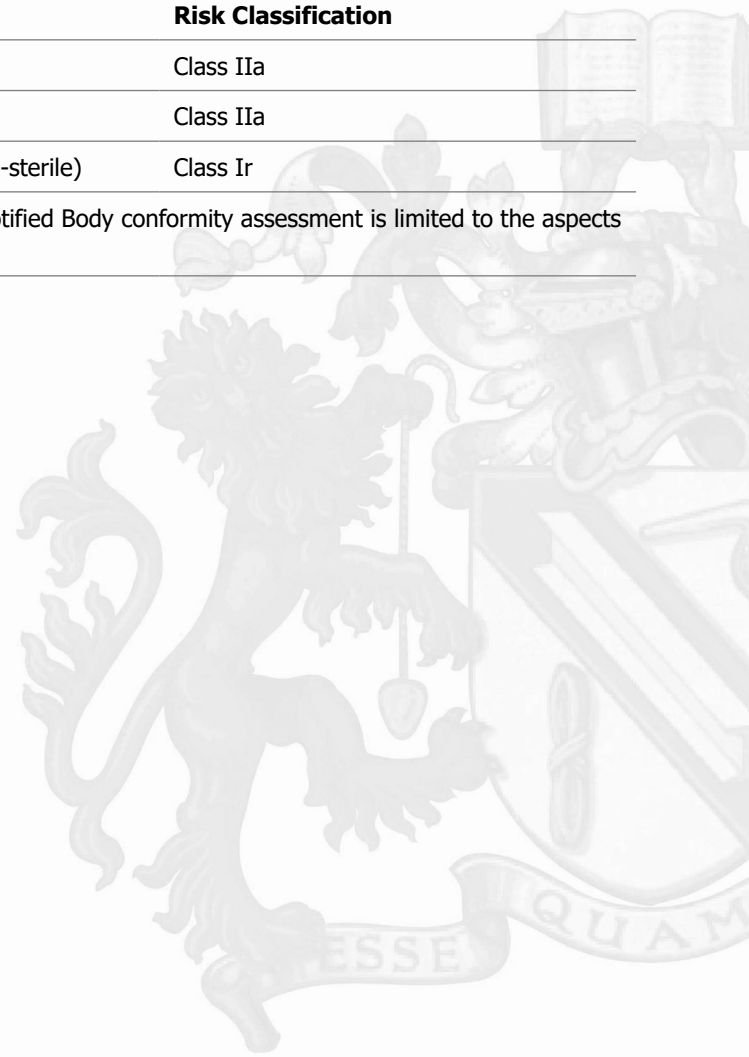
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Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Reusable rigid medical endoscopes (non-sterile)	Class IIa
Reusable medical endoscope accessories – sheaths (non-sterile)	Class IIa
Reusable medical endoscope accessories – trocars, obturators (non-sterile)	Class Ir
For Class Ir devices (Class I re-usable surgical instruments), the Notified Body conformity assessment is limited to the aspects relating to the reuse of the device.	



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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
Current	3735908	Issued



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