



EU Quality Management Certificate



This is to certify that the company

H. + H. Maslanka Chirurgische Instrumente GmbH

Stockacher Straße 172
78532 Tuttlingen
Germany

SRN: DE-MF-000005600

has established, implemented and maintains a Quality Management System in accordance with

Annex IX, Chapter I and III of the Regulation (EU) 2017/745 **Conformity Assessment based on a Quality Management System and on Assessment of** **Technical Documentation**

for the device categories and products listed in the Annex of this certificate.

The conformity of the Quality Management System has been verified in an audit and is subject to regular surveillance in accordance with Annex IX, Chapter 1, Section 3.
Limitations to this certificate are listed in the Annex.

Devices listed in the Annex may bear the CE marking with the identification number of the Notified Body (0297).

For placing of devices of class III and devices class IIb implantable according to Article 52(4) subparagraph 2 listed in the Annex on the market, an additional certificate according to Annex IX, Chapter II is required.

Certificate registration no.	508298 MDR2017Q
Certificate ID	1000225429
Effective date	2026-09-29
Expiry date	2031-09-09
Frankfurt am Main,	2026-09-23



DQS Medizinprodukte GmbH

Sven Hoffmann
Managing Director



Accredited Body: DQS Medizinprodukte GmbH, August-Schanz-Str. 21, 60433 Frankfurt am Main
DQS Medizinprodukte GmbH is a Notified Body according to Regulation (EU) 2017/745
of the Council concerning medical devices with the Identification Number 0297.
The validity of the certification can only be verified by the QR-code.



Annex to EU Quality Management Certificate
SRN of Manufacturer: DE-MF-000005600
Certificate ID: 1000225429

Device categories and variants covered by this certificate according to Article 52:

Device category: **MDN 1208 - Non-active non-implantable instruments**
Product name: Punch single use
Risk classification: Is
Basic-UDI-DI: 42 511211 TD 18 BS
Intended purpose: Punches are used in combination with an endoscope and are intended solely for cutting or dissecting non-autologous (foreign) material such as suture material, tubing, or tissue. They are auxiliary instruments for invasive procedures and are not intended for use on human tissue.

Device category: **MDN 1208 - Non-active non-implantable instruments**
Product name: UniTip Applicator
Risk classification: IIa
Basic-UDI-DI: 42 511211 TD 14 BJ
Intended purpose: The UniTip Applicator is intended to assist the delivery of a powdered hemostatic agent STARSIL® HEMOSTAT to the treatment site in surgical procedures including endoscopic or laparoscopic surgeries.

Device category: **MDN 1208 - Non-active non-implantable instruments**
Product name: Transseptal needle and transseptal catheter
Risk classification: III
Basic-UDI-DI: 42 511211 TD 06 BK
Intended purpose: Transseptal needle is used only in combination with a transseptal catheter (safety sheath) for the crossing of the interatrial septum in order to perform transseptal left atrial or left ventricular procedures.

Device category: **MDN 1208 - Non-active non-implantable instruments**
Product name: Cardio biopsy forceps and cardio grasping forceps
Risk classification: III
Basic-UDI-DI: 42 511211 TD 07 BM
Intended purpose: Cardio-biopsy forceps are used in conjunction with a special introducer sheath/catheter for the biopsy (tissue extraction) on the human heart: Cardio-grasping forceps are used in conjunction with special introducer sheath/catheter for the transluminal extraction (foreign body removal) from the central circulatory system of the human body.

Device category: **MDN 1208 - Non-active non-implantable instruments**
Product name: Flex-Pusher I and II
Risk classification: III
Basic-UDI-DI: 42 511211 TD 08 BP
Intended purpose: The Flex-Pusher is an accessory compatible heart implants from Occlutech and is applied with special cardiac catheters in the human heart.



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Examinations and tests performed:

508298 A216852MED dated 2025-09-19
508298 A216855MED TD 18 STANZE ZUM EINMALGEBRAUCH dated 2026-05-20
D10384_B_TD_MDR_2022_08_07_Zietsch_FlexPusher.I.II_R1_sig
D10384_B_TD_MDR_2022_12_09_Zietsch_Punktionsnadel_R1_Rev1_sig
D10384_B_TD_MDR_2023_01_10_Jeske_Trans_Kath_R2_sig
02.22 D10384_B_TD_MDR_2022_08_07_Zietsch_Cardio_R2_sig

Further conditions for or limitations to the validity of the certificate:

In case of products that are placed on the market in sterile condition, the involvement of the Notified Body in the conformity assessment procedure is limited to the aspects of manufacture concerned with securing and maintaining sterile condition.

Reference to previous certificates:

Version	Date of Issue	Certificate-ID	Description of change
00	2026-09-29	1000225429	Initial Certification