



EU Technical Documentation Assessment 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 and maintains the required Technical Documentation in accordance with

Annex IX, Chapter II 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 Technical Documentation has been verified and confirmed in Conformity Assessment Procedures according to Article 52. The Technical Documentation is subject to regular surveillance. Limitations to this certificate are listed in the Annex.

Devices of class III and devices class IIb implantable according to Article 52(4) subparagraph 2 listed in the Annex may bear the CE marking with the identification number of the Notified Body (0297).

For placing devices listed in the Annex on the market, an additional certificate according to Annex IX, Chapter I and III is required.

Certificate registration no.	508298 MDR2017P
Certificate ID	1000332668
Effective date	2026-09-29
Expiry date	2028-05-07
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 Technical Documentation Assessment Certificate
SRN of Manufacturer: DE-MF-000005600
Certificate ID: 1000332668

Device categories and variants covered by this certificate:

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.

Examinations and tests performed:

D10384_B_TD_MDR_2022_12_09_Zietsch_Punktionsnadel_R1_Rev1_sig
D10384_B_TD_MDR_2023_01_10_Jeske_Trans_Kath_R2_sig

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

n/a

Reference to previous certificates:

Version	Date of Issue	Certificate-ID	Description of change
00	2026-09-29	1000332668	Initial Certification