EU Quality Management Certificate

This is to certify that the company

Stockert GmbH

Bötzinger Straße 31
79111 Freiburg
Germany

SRN: DE-MF-000006981

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.	288842 MDR2017Q
Certificate ID	1000184049
Effective date	2024-07-03
Expiry date	2028-11-01
Frankfurt am Main,	2024-07-03

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-094

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Michael Bothe
Head of Certification Body
(active medical devices)

Szymon Kurdyn
Head of Certification Body
(non-active medical devices)

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.

420.90 Version 6.0

Annex to EU Quality Management Certificate
SRN of Manufacturer: DE-MF-000006981
Certificate ID: 1000184049

Device categories and variants covered by this certificate:

Device category:	**MDA 0305 - Active non-implantable devices for stimulation or inhibition**
Product name:	Stimuplex® HNS 12
Risk classification:	IIa
Basic-UDI-DI:	426016637020703200132
Intended purpose:	The nerve stimulator is intended for localisation of nerves.

Device category:	**MDN 1202 - Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis**
Product name:	G4-Tubing
Risk classification:	IIa
Basic-UDI-DI:	4260166370106041001ZT
Intended purpose:	The tubing is intended to be used together with the G4 Pump to deliver irrigation solution to irrigated catheters.

Examinations and tests performed:
288842_ A211310MED_01 dated 2023-10-26
288842_ A211310MED_02 dated 2023-06-21
288842_ A212967MED_03 G4-Tubing dated 2024-06-24

Further conditions for or limitations to the validity of the certificate:
n/a

Reference to previous certificates:

Revision	Date of Issue	Certificate-ID	Description of change
01	2023-11-02	170782314	New certificate templates
02	2024-05-08	1000169513	Addition of the product G4-Tubing