EU-Quality Management Certificate

This is to certify that the company

CGR Minnesota, LLC

6288 Claude Way East
Inver Grove Heights, MN, 55076
United States of America

AJW Technology Consulting GmbH

Breite Strasse 3
40213 Düsseldorf
Germany

has implemented a complete Quality Management System for each phase from Design to Final Testing of the products.

Through an audit, documented in a report, carried out by DQS Medizinprodukte GmbH, the proof was provided that this quality management system meets the requirements according to

Annex XI Part A of the Regulation (EU) 2017/745

CONFORMITY ASSESSMENT PROCEDURE ON THE BASIS OF A PRODUCTION QUALITY ASSURANCE

regarding the medical devices listed in the Annex:
The manufacturer shall be subject to surveillance in accordance with Annex XI, Part A, Section 7.
The CE marking with the identification number of the Notified Body (0297) may be affixed on the devised listed on the certificate.

In case of devices placed on the market in sterile condition, devices with a measuring function or for devices which are reusable surgical instruments, the involvement of the Notified Body in these procedures shall be limited: in case of products that are placed on the market in sterile condition, limited to the aspects of manufacture concerned with securing and maintaining sterile condition; in the case of devices with a measuring function limited to the aspects related to the conformity of the devices with the metrological requirements; in the case of reusable surgical instruments limited to the aspects related to reuse, in particular cleaning, disinfection, sterilisation, maintenance and functional testing, as well as the related instructions for use.

Certificate registration no.	US-MF-000014503
Certificate ID	170779386
Previous certificate-ID	n/a
Effective date	2022-02-24
Expiry date	2027-02-23
Frankfurt am Main,	2022-02-24

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

DQS Medizinprodukte GmbH

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Head of Certification Body

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DQS Medizinprodukte GmbH is a Notified Body according to Regulation (EU) 2017/745 of the Council concerning medical devices with the Identification Number 0297.

420.93 Version 1.0

Annex to EU Quality Management Certificate
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Product name	Risk class	Intended Use
Steri -Tamp®	Is	The Steri -Tamp® purpose is to provide means to identify if a previously opened vial, IV bottle or bag has been tampered with.

Examinations and tests performed (e.g. Reference to relevant CS, harmonised standards, test reports and audit report):
489307_A209141MED_01MDR dated 2021-10-18
420_12e_Report_TechnicalFileReview_CGR_V3 dated 2022-02-22

Reference to the relevant parts of the technical documentation or other certificates required for the placing on the market of the device or devices covered:
n/a

Conditions or limitations regarding the validity of the certificate:
n/a