EU Certificate

Quality Management System
REGULATION (EU) 2017/745 on Medical Devices, Annex IX Chapter I, Section 2 and 3 and Chapter III

TÜVRheinland®

Registration No.: HZ 2247538-1

Manufacturer:
Stryker Instruments,
a division of Stryker Corporation
1941 Stryker Way
Portage MI 49002
USA

EUDAMED Single Registration No.: No Registration number available yet.

Products:

Products of class IIb:
K020199 - Electrosurgical Devices, Mono- and Bipolar
Electrosurgical Devices, Mono- and Bipolar - Others

Products of class IIa:
K020201 - Electrosurgical Ultrasonic Instrumentary, Single-Use
P090880 - Hip Prosthesis - Accessories
P099002 - Orthopaedic Cements, Fitting and Application Devices and Kits
Q010501 - Dental Burs and Abrasive Disks, Single-Use
V0103 - Blades, Single-Use
V0199 - Cutting Devices, Single-Use - Others
Z120190 - Various Instruments for General and Multidisciplinary Surgery
Z120590 - Various Cardiologic and Cardiosurgery Instruments
Z121305 - Instruments for Motorized Orthopaedic Surgery System
Z121390 - Various Orthopaedic and Traumatology Instruments

The Notified Body hereby declares that the requirements of Annex IX, Chapter I, Section 2 and 3 of the REGULATION (EU) 2017/745 have been met for the listed products. The above named manufacturer has established and applies a quality management system, which is subject to periodic surveillance, defined by Annex IX, Chapter I, Section 3 of the aforementioned regulation. The requirements of Annex IX, Chapter III are fulfilled. If class III devices or class IIb implantable devices referred to in the second subparagraph of Article 52(4) are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 4.9 is required before placing them on the market.

Report No.: 234116460-20

Effective date: 2021-04-13

Expiry date: 2025-05-12

Issue date: 2021-04-13

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-091

Signature Not Verified
Dokument podpisany przez Małgorzata Adamczyk
Data: 2022.05.06 08:38:22 CEST

Dr. T. Kiessling
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/745 concerning medical devices with the identification number 0197.

EU Certificate

Quality Management System
REGULATION (EU) 2017/745 on Medical Devices, Annex IX Chapter I, Section 2 and 3 and Chapter III

TÜVRheinland®

Registration No.: HZ 2247538-1

Manufacturer:

Stryker Instruments,
a division of Stryker Corporation
1941 Stryker Way
Portage MI 49002
USA

Products of class Is:
The scope of certification is limited to the aspects relating to establishing, securing and maintaining sterile conditions

A0380 - Tubular Devices - Accessories
C900103 - Arterial Access Haemostasis, Percutaneous Systems
M040406 - Dressings Polyurethane
P099002 - Orthopaedic Cements, Fitting and Application Devices and Kits
Q030499 - Otology Devices Others
T0204 - Surgical Gowns
T020699 - Surgical Face Masks - Others
Z121390 - Various Orthopaedic and Traumatology Instruments

Authorised representative(s):

Stryker European Operations Limited
Anngrove, IDA Business & Technology Park
Carrigtwohill, Co. Cork
T45 HX08
Ireland

Certificate history		
Revision:	Description:	Issue date:
1	Initial revision	2021-02-28
2	Scope, Products of class IIb and IIa added – ENMD K020199, Z120190, Z121390	2021-03-15
3	Scope correction – class IIa ENMD A0499 removed, class Is ENMD M040406, Q030499 added	2021-04-13

Report No.: 234116460-20

Effective date: 2021-04-13

Expiry date: 2025-05-12

Issue date: 2021-04-13

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-091

Dr. T. Kiessling
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/745 concerning medical devices with the identification number 0197.