Business Stream Products
Certification Department

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LGA
Precisely Right.

TÜV Rheinland LGA Products GmbH • 51105 Köln

STORZ MEDICAL AG
Lohstampfestrasse 8
8274 Tägerwilen
Switzerland

Contact

Tel. +49 911 655-5225
Mail: medical-products@de.tuv.com

Date May 27, 2024

Notified Body Confirmation Letter
Reference: MDR Application 2024-02-07, Order #1160720

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

This letter confirms that **TÜV Rheinland LGA Products GmbH**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **0197** on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

STORZ MEDICAL AG
Lohstampfestrasse 8
8274 Tägerwilen
Switzerland
SRN Number (if available): CH-MF-000014374

The devices covered by the formal application and the written agreement mentioned above are identified in the tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after May 26, 2021 but before March 20, 2023 without having been withdrawn, this letter also confirms that the manufacturer either signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by March 20, 2023 for the relevant devices.

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The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- May 26, 2026 for Class III custom-made implantable devices
- December 31, 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- December 31, 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- December 31, 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body

Digital unterschrieben von Karsten Kluge
Datum: 2024.05.27 23:14:11 +02'00'

i.V. Dr. Karsten Kluge
Certification body

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
MODULITH SLX-F2 07630039101442	IIb non-implantable	MODULITH SLX-F2 REF: 29000	HD 60146857 0001 #0197
MODULITH SLX-F2 07630039101459	IIb non-implantable	MODULITH SLX-F2 REF: 29000	HD 60146857 0001 #0197
MODULITH SLX-F2 07630039101466	IIb non-implantable	MODULITH SLX-F2 REF: 29000	HD 60146857 0001 #0197
MODULITH SLK 07630039101503	IIb non-implantable	MODULITH SLK REF: 27000	HD 60146857 0001 #0197
MODULITH SLK 07630039101497	IIb non-implantable	MODULITH SLK REF: 30000	HD 60146857 0001 #0197
MODULITH SLC 07630039101510	IIb non-implantable	MODULITH SLC REF: 33000	HD 60146857 0001 #0197
MASTERPULS MP50 07630039101565	IIa	MASTERPULS MP50 REF:23231.0100	HD 60146857 0001 #0197
MASTERPULS MP100 07630039101541	IIa	MASTERPULS MP100 REF:23232.0100, 23232.0102 23232.0103	HD 60146857 0001 #0197

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
MASTERPULS MP200 07630039101572	IIa	MASTERPULS MP200 REF:19576.0100	HD 60146857 0001 #0197
MASTERPULS MP200 07630039101589	IIa	MASTERPULS MP200 REF:19576.0101	HD 60146857 0001 #0197
D-ACTOR 100 07630039101558	IIa	D-ACTOR 100 REF:23300.0100, 23300.0103, 23300.0104	HD 60146857 0001 #0197
D-ACTOR 200 07630039101596	IIa	D-ACTOR 200 REF:19700.0100	HD 60146857 0001 #0197
D-ACTOR 200 07630039101602	IIa	D-ACTOR 200 REF:19700.0101, 19700.0103	HD 60146857 0001 #0197
MASTERPULSE ONE 7630039101657	IIa	MASTERPULS ONE REF:27800.0001, 27800.0003	HD 60146857 0001 #0197
MASTERPULSE ONE 07630039101664	IIa	MASTERPULS ONE REF:27800.0002, 27800.0012	HD 60146857 0001 #0197
CHATTANOOGA Intelect RPW Lite 07630039101732	IIa	CHATTANOOGA Intelect RPW Lite REF: 30680.0001	HD 60146857 0001 #0197
CHATTANOOGA Intelect RPW Lite 07630039101749	IIa	CHATTANOOGA Intelect RPW Lite REF: 30680.0002	HD 60146857 0001 #0197
CHATTANOOGA Intelect RPW Lite 07630039101756	IIa	CHATTANOOGA Intelect RPW Lite REF: 30680.0003	HD 60146857 0001 #0197
D-ACTOR ONE 07630039101671	IIa	D-ACTOR ONE REF: 30943.0001	HD 60146857 0001 #0197
D-ACTOR ONE 07630039101688	IIa	D-ACTOR ONE REF: 30943.0002	HD 60146857 0001 #0197
CHATTANOOGA Mobile 2 RPW - 2905 07630039101725	IIa	CHATTANOOGA Mobile 2 RPW - 2905 REF: 27399.0001, 27399.0002	HD 60146857 0001 #0197
DUOLITH SD1 T-TOP 07630039101626	IIb non-implantable	DUOLITH SD1 T-TOP [010x] REF: 21362.0100, 21362.0102, 21362.0103	HD 60146857 0001 #0197
CELLIMPACT 07630039101695	IIb non-implantable	CELLIMPACT REF:27100.0100	HD 60146857 0001 #0197
CHATTANOOGA Intelect F-SW - 21095 07630039101763	IIb non-implantable	CHATTANOOGA Intelect F-SW - 21095 REF: 26933.0011, 26933.0012	HD 60146857 0001 #0197
W-Medical Shockwave F1 07630039101701	IIb non-implantable	W-Medical Shockwave F1 REF: 27780.0011	HD 60146857 0001 #0197

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
DUOLITH SD1 TOWER 07630039101619	IIb non-implantable	DUOLITH SD1 TOWER REF:19880.0001, 19880.0005, 19880.0006	HD 60146857 0001 #0197
NEUROLITH 07630039101718	IIb non-implantable	NEUROLITH REF:31000.0001	HD 60146857 0001 #0197
MAGNETOLITH 07630039101633	IIa	MAGNETOLITH REF: 30500.0001, 30500.0002	HD 60146857 0001 #0197

Table 2: Devices covered by this letter and for which the NB is <u>NOT</u> responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/05/27	STORZ_CL607_2024-05-27	Initial issue
YYYY/MM/DD	XXXXXXXXX	Addition of device XYZ to the list
YYYY/MM/DD	XXXXXXXXX	Removal of device XYZ to the list

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EC Certificate

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60146857 0001

Report No.: 21256460 016

Manufacturer:
STORZ MEDICAL AG
Lohstampfestr. 8
8274 Tägerwilen
Schweiz

Products:
- Equipment for the extracorporeal induced shock wave and pressure pulse therapy for stationary and mobile use
- Equipment for the extracorporeal magnetotransduction therapy
- X-ray application devices (without radiation components)

(see attachment for products included)
Replaces Certificate, Registration No.: HD 60140661 0001

Expiry Date: 2024-05-26

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2020-02-18

Date: 2020-02-18

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

Dipl.-Ing. I. Munkler

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

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Doc. 1/3, Rev. 1

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60146857 0001
Report No.: 21256460 018

Manufacturer: STORZ MEDICAL AG
Lohstampfestr. 8
8274 Tägerwilen
Schweiz

Equipment for the extracorporeal induced shock wave therapy for stationary and mobile use:
- MODULITH SLK
  with options
  - LITHOTRACK
  - US-SET

- MODULITH SLX-F2
  with options
  - C-ARM C-MX
  - US-SET
  - StorM-Touch
  - MONITORARM

Equipment for the extracorporeal induced cardiac shock wave therapy for treatment of ischemic heart disease:
- MODULITH SLC

Date: 2020-05-06

Notified Body

Roland Gruber

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

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Doc. 2/3, Rev. 1

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60146857 0001
Report No.: 21256460 018

Manufacturer: STORZ MEDICAL AG
Lohstampfestr. 8
8274 Tägerwilen
Schweiz

X-ray application devices (without radiation components):
- C-MX

Equipment for the extracorporeal pneumatically operated ballistic pressure wave therapy:
- MASTERPULS MP100
- MASTERPULS MP200
- MASTERPULS MP50
- MASTERPULS ONE
- D-ACTOR 100
- D-ACTOR 200
- D-ACTOR 50
- D-ACTOR ONE
- CHATTANOOGA MOBILE RPW - 2805
- CHATTANOOGA MOBILE 2 RPW - 2905
- CHATTANOOGA INTELECT RPW Lite

Notified Body

Date: 2020-05-06

Roland Gruber

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

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Doc. 3/3, Rev. 1

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60146857 0001
Report No.: 21256460 018

Manufacturer: STORZ MEDICAL AG
Lohstampfestr. 8
8274 Tägerwilen
Schweiz

Equipment for the extracorporeal induced shock and pressure wave therapy for stationary and mobile use:
- DUOLITH SD1 T-Top [001x]
- DUOLITH SD1 T-Top [010x]
- DUOLITH SD1 Tower
- CELLACTOR SC1 T-Top
- CELLACTOR SC1 Tower
- CELLIMPACT
- CHATTANOOGA INTELECT F-SW - 21095
- W-MEDICAL SHOCKWAVE F1
- NEUROLITH
- eSparkPower

Equipment for the extracorporeal magnetotransduction therapy
- MAGNETOLITH
- Gymna Magnacure 300

Date: 2020-05-06

Notified Body

Roland Gruber

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle