Anexa nr. 1
La Procedurile administrative pentru notificarea dispozitivelor medicale care deţin marcajul CE

Către Agenţia Medicamentului
şi Dispozitivelor Medicale

NOTIFICARE
pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale
nr. __ din __.__.2023

Solicitantul SC "Denolga Medical" SRL, cu sediul mun. Chișinău, str. Grenoble, 149A, tel/fax: +373 22 260-602, +373 22 260-601, e-mail: olesea.cucerenco@yahoo.com,
solicit înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii şi tipuri de dispozitive medicale pentru introducerea și punerea la dispoziție pe piață a:

Se anexează următoarele acte:

Conform anexei Excel

EC DECLARATION OF CONFORMITY, STORZ MEDICAL AG, Elveția – 2 file;

EC CERTIFICATE Directive 93/42/EEC Annex II, excluding Section 4 Full Quality Assurance System Medical Devices, STORZ MEDICAL AG, Elveția, 4 file/ buc.

Grading of the Medical Devices into generic family groups/ product subcategories, STORZ MEDICAL AG – 4 file/ buc;

Lista dispozitivelor medicale (versiunea Excel);

Data __.__.2023 Semnătura _____

Tabelul de recepționare a notificării

(se completează de către Agenție în momentul depunerii notificării de către solicitant)

Comentarii cu privire la acceptul/refuzul recepționării notificării, inclusiv motivul refuzului	Digitally signed by Gherman Irina Date: 2023.11.21 10:37:21 EET Reason: MoldSign Signature Location: Moldova
Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării)	
Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	
Semnătura persoanei responsabile	

Anexa nr. 2
La Procedurile administrative pentru notificarea dispozitivelor medicale care deţin marcajul CE

Către Agenția Medicamentului și Dispozitive Medicale

DECLARAŢIE PE PROPRIE RĂSPUNDERE

Solicitant: **SC „Denolga Medical" SRL**, cu sediul mun. Chișinău, str. Grenoble 149A,

declar pe proprie răspundere, cunoscând prevederile art. **352[1]**, Codul Penal al Republicii Moldova cu privire la falsul în declaraţii, că documentele și datele furnizate pentru notificarea dispozitivului medical:

Conform anexei Excel

Sunt autentice și corespund realității.

Cucerenco Olesea, jurisconsult
Numele, prenumele şi funcţia *Semnătura*
_____

Data __.__.2023

STORZ MEDICAL

EG-KONFORMITÄTSERKLÄRUNG · EC DECLARATION OF CONFORMITY
DECLARACIÓN CE DE CONFORMIDAD · DICHIARAZIONE CE DI CONFORMITÀ

Name und Adresse des Herstellers: /
Name and address of the manufacturer: /
Nombre y dirección del fabricante: /
Nome e indirizzo del fabbricante:

STORZ MEDICAL AG
Lohstampfestr. 8
8274 Tägerwilen
SWITZERLAND

Wir erklären in alleiniger Verantwortung, dass / We declare under our sole responsibility that /
Declaramos bajo nuestra única responsabilidad que / Dichiariamo sotto la sola responsabilità che

das Medizinprodukt: /
the medical device: /
el producto sanitario: /
il dispositivo medico:

MASTERPULS® MP100

Produktcode: 0S	**REF 23232.0100**
Product code: 0S	**REF 23232.0100**
Código del producto: 0S	**REF 23232.0100**
Codice prodotto: 0S	**REF 23232.0100**

der Klasse: /
of class: /
de la clase: /
di classe:

IIa

nach Anhang IX der Richtlinie 93/42/EWG / according to annex IX of directive 93/42/EEC /
conforme al anexo IX de la directiva 93/42/CEE / secondo l'allegato IX della direttiva 93/42/CEE

den einschlägigen Bestimmungen der Medizinprodukte-Richtlinie 93/42/EWG und deren Umsetzungen in nationale Gesetze entspricht. Die Erklärung gilt in Verbindung mit dem zum Produkt gehörigen Endabnahmeprotokoll.

meets the provisions of the directive 93/42/EEC and its transpositions in national laws which apply to it. The declaration is valid in connection with the final inspection report of the device.

cumple las disposiciones pertinentes de la Directiva de productos sanitarios 93/42/CEE y sus transposiciones a la legislación nacional. La presente declaración se aplicará junto con el protocolo de aceptación final que corresponda al producto.

soddisfa tutte le disposizioni della direttiva 93/42/CEE e della loro trasposizione nel diritto nazionale che lo riguardano. Questa dichiarazione è valida in congiunzione con il rapporto di ispezione finale del prodotto.

Konformitätsbewertungsverfahren: /
Conformity assessment procedure: /
Procedimiento para la evaluación de la conformidad: /
Procedura di valutazione della conformità:

Richtlinie 93/42/EWG, Anhang II, ohne Abschnitt 4
Directive 93/42/EEC, Annex II, excluding section 4
Directiva 93/42/CEE, Anexo II, sin el apartado 4
Direttiva 93/42/EEC, Allegato II, senza sezione 4

Gültigkeitsdatum: /
Validity date: /
Fecha da validez: /
Data di validità:

26.05.2024

STORZ MEDICAL AG
Tel: +41(0)71 677 45 45
Fax: +41(0)71 677 45 05
Lohstampfestr. 8 CH-8274 Tägerwilen

Benannte Stelle: /
Notified Body: /
Organismo notificado: /
Organismo notificato:

TÜV Rheinland LGA Products GmbH
Tillystraße 2
90431 Nürnberg
GERMANY
CE 0197

EU Bevollmächtigter: /
EU authorized representative: /
Representante autorizado de la UE: /
Rappresentante autorizzato UE:

STORZ MEDICAL Deutschland GmbH
Victor-Goerttler-Straße 11
07745 Jena
GERMANY

Tägerwilen, 25-05-2021

Ort, Datum / Place, date / Lugar, fecha / Luogo, data

Dr. G. Heine, CEO

Name und Funktion / Name and function / Nombre y cargo / Nome e funzione

TÜVRheinland®

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.

TÜVRheinland®

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

TÜVRheinland®

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

TÜVRheinland®

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

STORZ MEDICAL

Erklärung / *Declaration*

Einteilung der Medizinprodukte in generische Produktgruppen / Produktunterkategorien
Grading of the Medical Devices into generic family groups / product subcategories

Die Firma: / *The Company:*

STORZ Medical AG
Lohstampfestrasse 8
CH-8274 Tägerwilen

erklärt: / *declares:*

Unsere Medizinprodukte werden laut dem Dokument "Guidance on Notified Body's Tasks of Technical Documentation Assessment on a Representative Basis" NBOG (Notified Body Operation Group) BPG 2009-4 in folgende generische Produktgruppen bzw. Produktunterkategorien eingeteilt:

*Our Medical Devices are categorized into generic product families' resp. product subcategories, according to the document "*Guidance on Notified Body's Tasks of Technical Documentation Assessment on a Representative Basis*" NBOG (Notified Body Operation Group) BPG 2009-4 as follows:*

Generische Produktgruppe *Generic Product Family*	**MD 1404:** **Produkte zur (extrakorporalen) Schockwellentherapie (Lithotripter)** *Devices for (extracorporal) shock-wave therapy (lithotripsy)*	**Klassifizierung** *Device Classification:*	IIb

Produktunterkategorie *Product Subcategory*	**Medizinproduktename** *Medical Devices Name*	**Produkt-aktencode** *Device Record Code*	**Artikelnummer** *Part Number*	**Ref.#*** *Ref.#*
Lithotriptor, extracorporeal GMDN: 16758	MODULITH SLK	0L	27000	n/a
		1L	30000	
	Modulith SLC	0Q	33000	
	Modulith SLX-F2	0R	29000	
Electromechanical Orthopaedic extracorporeal acoustic and pressure wave therapy system GMDN: 47995		TT	n/a	I
	DUOLITH SD1 T-Top Alternative CELLIMPACT		21362.010x 27100.010x	II
	DUOLITH SD1 T-Top		27223.00xx	III
	Alternative Chattanooga Intelect F-SW – 21095		26933.00x1	
	Alternative Chattanooga Intelect F-SW USA		26933.00x2	
	Alternative W-Medical Shockwave F1		27780.00xx	
	DUOLITH SD1 Tower	BT	19900.00xx	n/a
	eSparkPower	EH	31500.000x	n/a

Generische Produktgruppe *Generic Product Family*	**MD 1401:** **Geräte mit ionisierender Strahlung** *Devices utilising ionizing radiation*	**Klassifizierung** *Device Classification:*	IIb

Produktunterkategorie *Product Subcategory*	**Medizinproduktename** *Medical Devices Name*	**Produkt-aktencode** *Device Record Code*	**Artikelnummer** *Part Number*	**Ref.#*** *Ref.#*
Table, x-ray system, diagnostic, general purpose, powered GMDN: 40655	C-MX	1M	23805.000x	n/a

Generische Produktgruppe *Generic Product Family*	**MD 1103:** **Produkt zur Stimulation oder Hemmung** *Devices for stimulation or inhibition*	**Klassifizierung** *Device Classification*	IIa & Neurolith IIb

Produktunter-kategorie *Product Subcategory*	**Medizinproduktename** *Medical Devices Name*	**Produkt-akten-code** *Device Record Code*	**Artikelnummer** *Part Number*	**Ref.#*** *Ref.#*
Orthopaedic extracorporeal shock wave therapy system GMDN: 47032	MASTERPULS ONE Alternative CHATTANOOGA Intelect RPW Lite Alternative Gymna Shockmaster 100	DS	27800.00xx 30700.000x 31086.000x	n/a
	MASTERPULS MP50	AS	n/a 23231.010x	I II
	CHATTANOOGA MOBILE RPW – 2805	CS	22715.000x	I

	CHATTANOOGA MOBILE 2 RPW – 2905		27399.000x	II
	MASTERPULS MP100 Alternative OrthoPulse Ultra	0S	23232.010x 26882.010x	II
	MASTERPULS MP200	BS	19576.010x	II
Pressure-wave skin contouring system GMDN: 47979	D-ACTOR ONE	DS	30943.000x	n/a
	D-ACTOR 50	AS	n/a 23297.010x	I II
	D-ACTOR 100	0S	23300.010x	II
	D-ACTOR 200	BS	19700.010x	II
	CELLACTOR SC1 T-Top	TT	22896.010x	II
	CELLACTOR SC1 Tower	BT	25500.00xx	n/a
	CHATTANOOGA MOBILE 2 RPW USA	CS	27399.0002	II
Stimulator GMDN: 13762	NEUROLITH	BTN	31000.xxxx	n/a
	MAGNETOLITH Alternative Gymna Magnacure 300	TTM	30500.000x 31850.000x	n/a

* Andere Dokumente beinhalten diese Referenznummer, um eindeutig auf die Artikelnummern in diesem Dokument zu verweisen.

Other documents contain this reference number for unique reference to part numbers shown in this document.

Tägerwilen, den 23. September 2019 / September 23, *2019*

Tim Jessat
Senior Manager Regulatory Affairs

STORZ MEDICAL AG
Tel: +41(0)71 677 45 45
Fax: +41(0)71 677 45 05
Lohstampfestr. 8 CH-8274 Tägerwilen

Anexa nr. 3

Nr.	Numărul de catalog (referință)*	Denumire generică (denumirea dispozitivului)	Denumire comercială (brand)*	Modelul	Cod GMDN*	
1	23232.0100	MASTERPULS MP100	STORZ MEDICAL AG	23232.0100	47032	IIa