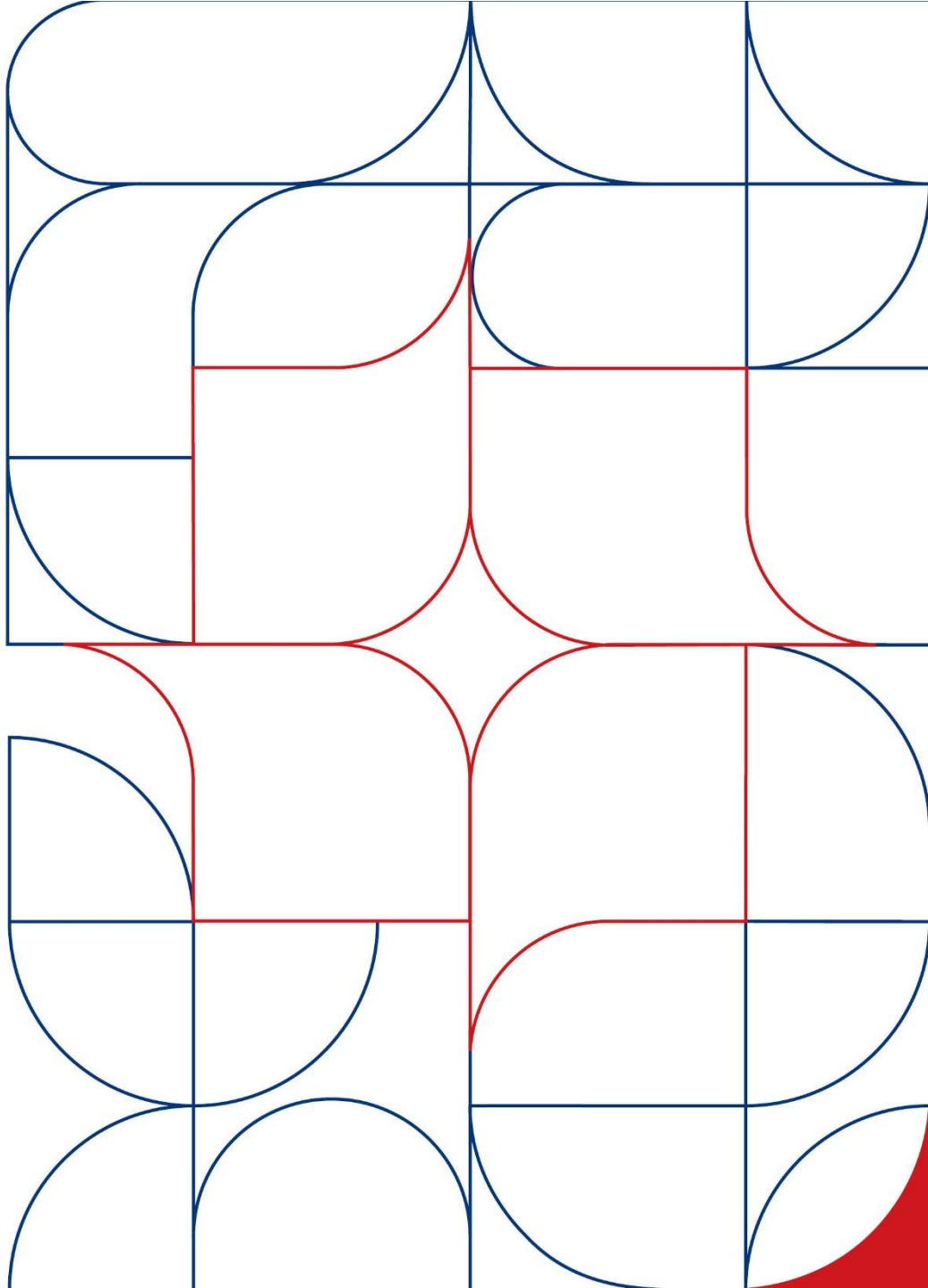
MDR EU sertifikati i načini ocenjivanja u zavisnosti od klase rizika

Sanja Jović

03.07.2024.

PRIVREDNA KOMORA SRBIJE
1857



MEDICAL DIVICES REGULATION (MDR)

- REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC
- MDR predstavlja propis koji reguliše proizvodnju i distribuciju medicinskih sredstava u Evropskoj uniji
- ima za cilj da osigura da medicinska sredstva nemaju negativan uticaj na zdravlje ljudi
- MDR je naslednik prethodne Direktive o medicinskim sredstvima (MDD)

MDR vs MDD

- Širi obim i prelazak velikog broja medicinskih sredstava u više klase
- Stroža klinička evaluacija
- Implementacija jedinstvene identifikacije proizvoda (UDI)
- Registracija u bazi podataka EUDAMED
- Zahtevniji post-tržišni nadzor
- Pojačani regulatorni zahtevi
- Odgovornosti za usklađenost sa propisima na nivou organizacije
- Prošireni opseg proizvoda koji nemaju medicinsku namenu

CE ZNAK

- Prema MDR, da bi se medicinsko sredstvo legalno prodavalo na tržištu EU, mora imati CE oznaku
- da bi dobilo CE oznaku, medicinsko sredstvo se podvrgava proceni usaglašenosti, kojom se utvrđuje da li je usaglašeno sa zahtevima MDR-a

ŠTA U TOM POSTUPKU TREBA PRVO DA URADIMO?

Pitanja:

Da li se naš proizvod uklapa u definiciju medicinskog sredstva?
Koja je klasa našeg medicinskog sredstva?

Zavisno od odgovora na ova pitanja - zavisi i postupak koji primenjujemo

DEFINICIJA MEDICINSKOG SREDSTVA

‘medical device’ means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, **for human beings** for one or more of the following **specific medical purposes:**

— diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,

— diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,

— investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,

— providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations,

DEFINICIJA MEDICINSKOG SREDSTVA

and which **does not achieve its principal intended action by pharmacological, immunological or metabolic means**, in or on the human body, but which may be assisted in its function by such means.

....

Napomena: Za potpunu definiciju videti MDR, član 2

KLASIFIKACIJA

- MDR uvodi promene u klasifikaciji medicinskih sredstava (prelazak velikog broja medicinskih sredstava u višu klasu)
- Klasa rizika medicinskog sredstva zasnovana je na percipiranom riziku koji se odnosi na potencijalni uticaj koji medicinsko sredstvo može imati na ljudsko telo
- Klase definisane u odnosu na rizik – klasa I sa najmanjim rizikom, klasa III sa najvećim rizikom

KAKO SE ODREĐUJU KLASE PO MDR?

- Klasifikacija se vrši u skladu sa Aneksom VIII
- sistem zasnovan na pravilima
- 22 pravila svrstana u 4 grupe – neinvazivna MS, invazivna MS, aktivna MS, specijalna pravila
- primena pravila – u odnosu na nameravanu upotrebu
- ukoliko je primenljivo više pravila – uvek se određuje najviša klasa

NAČINI OCENJIVANJA U ZAVISNOSTI OD KLASE RIZIKA

Klasa I
- najniži rizik
- proizvođač sam dodeljuje CE znak, bez učešća notifikovanog tela
- proizvođač izdaje Deklaraciju o usaglašenosti

Klase I koje se označavaju sa Is, Im, Ir
- viši nivo rizika u odnosu na „običnu“ klasu I
- u oceni usaglašenosti učestvuje notifikovano telo

Klasa Is - sterilna medicinska sredstva
Primeri sterilni špricevi, igle, rukavice za pregled, sterilna gaza, sterilne komprese

Klasa Im - medicinska sredstva sa funkcijom merenja
Primeri: termometri, špricevi za odmeravanje, kašičice/posudice za doziranje

Klasa Ir - medicinska sredstva koja se mogu ponovo obrađivati ili koristiti (*reprocessed or reusable*)
Primeri: hirurški instrumenti, koji se čiste i sterilišu pre ponovne upotrebe

Class I, Im, Is and Ir

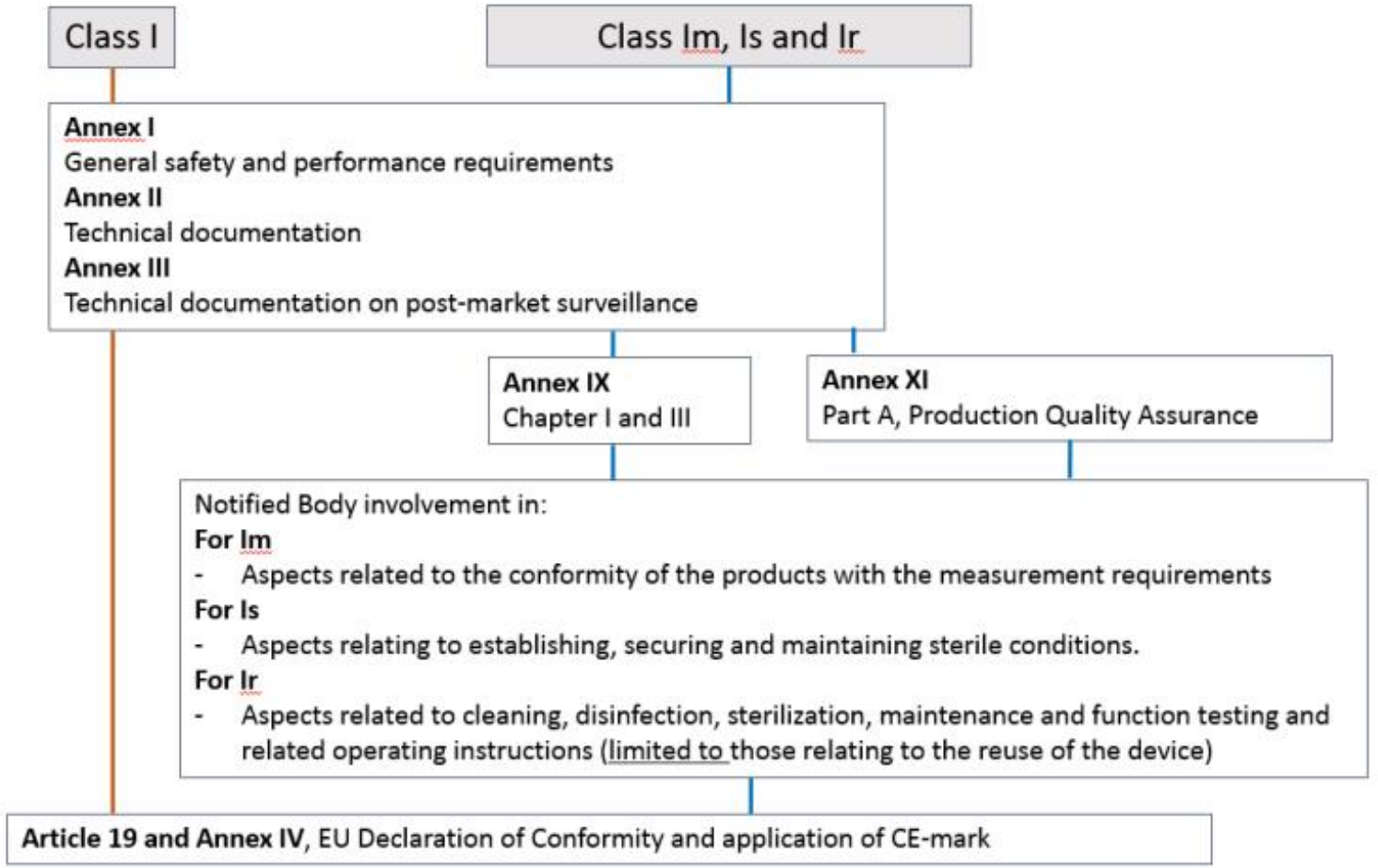


Figure 1. *Illustration of the conformity procedures for the assessment of Class I devices with and without NB involvement.*

NAČINI OCENJIVANJA U ZAVISNOSTI OD KLASE RIZIKA

Klasa IIa

- srednji rizik
- obavezno je učešće notifikovanog tela
- izdaje se EU serifikat od strane notifikovanog tela
- nakon toga proizvođač izdaje Deklaraciju o usaglašenosti

Primeri: rastvori za nazalnu primenu

NAČINI OCENJIVANJA U ZAVISNOSTI OD KLASE RIZIKA

Klasa IIb

- srednji do visoki rizik
- obavezno je učešće notifikovanog tela
- izdaje se EU serifikat od strane notifikovanog tela
- nakon toga proizvođač izdaje Deklaraciju o usaglašenosti

Primeri: penovi za insulin, preparati za rektalnu primenu

NAČINI OCENJIVANJA U ZAVISNOSTI OD KLASE RIZIKA

Klasa III

- visok rizik
- najstroži zahtevi MDR za ovu klasu u odnosu na sve druge
- obavezno je učešće notifikovanog tela
- izdaje se EU serifikat od strane notifikovanog tela
- nakon toga proizvođač izdaje Deklaraciju o usaglašenosti

Primeri: pejsmejkeri, implati za dojku, srčani zalisci, proizvodi koji sadrže lek

Medical Device Coordination Group (MDCG)

Borderline and Classification

Reference	Title	Publication
Manual on Borderline	Manual on borderline and classification under Regulations (EU) 2017/745 and 2017/746 v3 Background note on the use of the Manual on borderline and classification for medical devices under the Directives.	September 2023
MDCG 2022-5	Guidance on borderline between medical devices and medicinal products under Regulation (EU) 2017/745 on medical devices	April 2022
MDCG 2021-24	Guidance on **classification** of medical devices	October 2021
Helsinki Procedure	**Helsinki Procedure** for borderline and classification under MDR & IVDR	September 2021

MDCG 2021-24
Guidance on classification of medical devices
October 2021

https://health.ec.europa.eu/document/download/cbb19821-a517-4e13-bf87-fdc6ddd1782e_en?filename=mdcg_2021-24_en.pdf

MDCG 2019-15 rev.1 GUIDANCE NOTES FOR MANUFACTURERS OF CLASS I MEDICAL DEVICES December 2019 July 2020 rev.1

https://health.ec.europa.eu/document/download/349a2d4c-ea2a-4279-861c-7c063bc077e4_en?filename=md_guidance-manufacturers_en.pdf

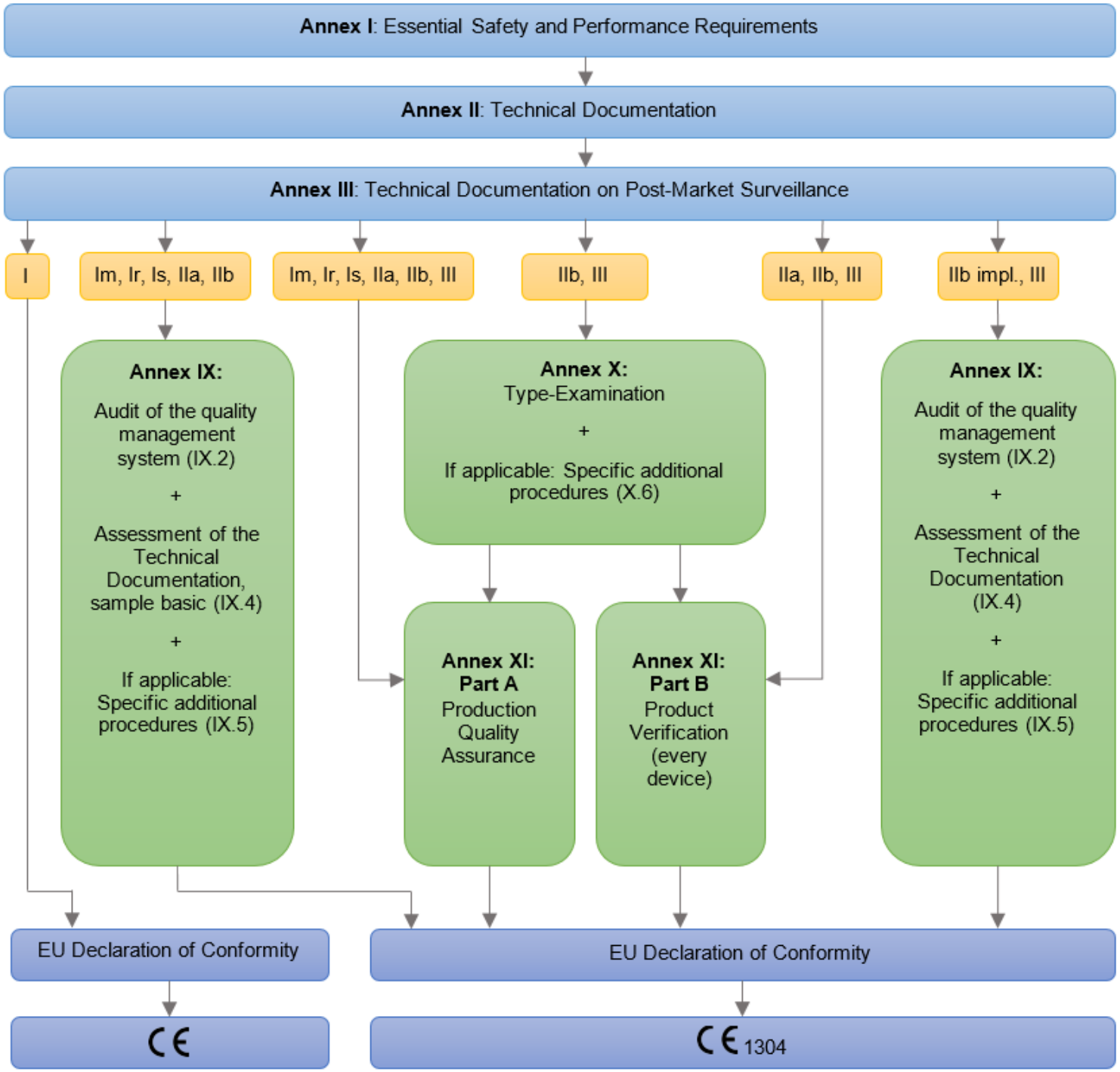
VRSTE POSTUPKA OCENJIVANJA

ANNEX IX
CONFORMITY ASSESSMENT BASED ON A QUALITY MANAGEMENT SYSTEM AND ON THE ASSESSMENT OF TECHNICAL DOCUMENTATION

ANNEX X
CONFORMITY ASSESSMENT BASED ON TYPE-EXAMINATION

ANNEX XI
CONFORMITY ASSESSMENT BASED ON PRODUCT CONFORMITY VERIFICATION
Part A Production Quality Assurance, Part B Product Verification

SPECIFIC PROCEDURES


Annex I: Essential Safety and Performance Requirements
Annex II: Technical Documentation
Annex III: Technical Documentation on Post-Market Surveillance
I
Im, Ir, Is, IIa, IIb
Im, Ir, Is, IIa, IIb, III
IIb, III
IIa, IIb, III
IIb impl., III
Annex IX:
Audit of the quality management system (IX.2)
+
Assessment of the Technical Documentation, sample basic (IX.4)
+
If applicable: Specific additional procedures (IX.5)
Annex X:
Type-Examination
+
If applicable: Specific additional procedures (X.6)
Annex XI: Part A
Production Quality Assurance
Annex XI: Part B
Product Verification (every device)
Annex IX:
Audit of the quality management system (IX.2)
+
Assessment of the Technical Documentation (IX.4)
+
If applicable: Specific additional procedures (IX.5)
EU Declaration of Conformity
EU Declaration of Conformity
CE
CE 1304

VRSTE EU SERTIFIKATA

EU Certificate – Quality Management System
EU Certificate – Production Quality Assurance
EU Certificate – Product verification
EU Certificate – Technical documentation assessment
EU Certificate – Type-Examination if the type is compliant with the MDR

Primeri sertifikata po MDR

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QUALITY MANAGEMENT SYSTEM

EU-CERTIFICATE

Regulation (EU) 2017/745

Manufacturer:	LM-Instruments Oy Norrbyn rantatie 8 21600 Parainen Finland
Single registration number:	FI-MF-000006705
Conformity assessment procedure:	Regulation (EU) 2017/745 Annex IX
Device category:	MDN 1208 Non-active non-implantable instruments
Date of expiry:	11 September 2028

The manufacturer's quality management system covering the device category been assessed and approved in accordance with the Annex IX to Regulation (EU) 2017/745. Approval shall be valid until the expiry date provided that the manufacturer fulfills the obligations imposed by Annex IX in Regulation. The products covered by the certificate and the details related to the maintenance of this certificate are specified in the attachment to the certificate.

Date of issue: 11 September 2023

Alisa Siljander — Tiia Tuokko

Certificate no: **CR-03-1080-826-23**

Notified Body no. 0537:
Eurofins Electric & Electronics Finland Oy
Kivimiehentie 4
FI-02151 Espoo, FINLAND

Information about the examinations and tests as per MDR Annex XII, section 10, is available upon request from EES-medical@eurofins.fi.

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Attachment 1 to the certificate no: CR-03-1080-826-23

Manufacturer:	LM-Instruments Oy Norrbyn rantatie 8 21600 Parainen Finland
Other sites covered by the quality management system:	-
Single registration number:	FI-MF-000006705
Conformity assessment procedure:	Regulation (EU) 2017/745 Annex IX
Limitations to the validity of the certificate:	No limitations

The certificate covers the following products:

MD-codes:	MDN 1208 MDS 1006 MDT 2001, MDT 2002, MDT 2011	
Device category:	MDN 1208 Non-active non-implantable instruments	
Product name	*Product details*	
Periodontal hand instruments	Model	-
	Nomenclature code	L159001 Dental and periodontal curettes, reusable
	Risk class	Ir
Endodontic hand instruments	Model	-
	Nomenclature code	L159002 Dental excavators, reusable
	Risk class	Ir
Restorative hand instruments	Model	-
	Nomenclature code	L159002 Dental excavators, reusable
	Risk class	Ir

For class Im/Is/Ir devices quality management system has been audited limiting only to the aspects required under the article 52(7).

The validity and maintenance of this certificate require the surveillance performed by the notified body in accordance with the MDR Annex IX (3). The surveillance includes annual quality management system audits at the manufacturer's premises as well as regular unannounced audits. If necessary, all audits may be carried out at the premises of the manufacturer's suppliers and/or subcontractors. The surveillance also includes the assessment of the significant changes planned by the manufacturer and the assessment of the technical documentation in accordance with the notified body's sampling plan (IIa and IIb).

Eurofins Electric & Electronics Finland Oy is Notified Body no. 0537 under Regulation (EU) 2017/745.

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Attachment 1 to the certificate no: CR-03-1080-826-23

Date of issue of this attachment: 02 July 2024

Aliisa Siljander — Laura Petäjämäki

Change history of the certificate:				
Certificate no	**Revision**	**Status of the certificate**	**Date of issue**	**Description of the change**
CR-03-1080-826-23	01	Initial certification	11.09.2023	Initial revision
CR-03-1080-826-23	02	Supplemented	02.07.2024	Addition of new device groups (Ir) to the certificate based on the change notification NB-1080-M13 (Endodontic hand instruments, Restorative hand instruments).

Eurofins Electric & Electronics Finland Oy is Notified Body no. 0537 under Regulation (EU) 2017/745.

Primeri sertifikata po MDR

EU Certificate

Production Quality Assurance
REGULATION (EU) 2017/745 on Medical Devices, Annex XI, Part A

TÜVRheinland

Registration No.: DZ 2067318-1

Manufacturer: **Hubei V-Medical Products Co., Ltd.**
No. 67 Xianhong Road West, Xinlirenkou, Zhanggou Town, Xiantao City, 433012
Hubei, P.R. China

EUDAMED Single Registration No.: CN-MF-000011268

Products:

Products of class IIa:
M020102 - COTTON GAUZES, FOLDED
M020103 - LAPAROTOMY COTTON GAUZES

Products of Class Is:
The scope of certification is limited to the aspects relating to establishing, securing and maintaining sterile conditions
M020102 - COTTON GAUZES, FOLDED
M020104 - STARCHED COTTON GAUZES
M020199 - COTTON GAUZES – OTHER
M020201 - NON-WOVEN FOLDED GAUZES
M020202 - NON-WOVEN LAPAROTOMY GAUZES
M0299 - GAUZES - OTHER
M030101 - HYDROPHILIC GAUZE BANDAGES
M030301 - ELASTIC FIXING BANDAGES
M040301 - EYE PADS, COTTON OR NON-WOVEN MATERIALS
T020101 - INCISION DRAPES
T0202 - SURGICAL PROCEDURAL KITS (EXCLUDING SURGICAL INSTRUMENT KITS)
T020401 - STANDARD SURGICAL GOWNS
T0205 - NON-SURGICAL GOWNS (EXCLUDING PERSONAL PROTECTIVE EQUIPMENT - PPE)
T020603 - MEDICAL USE FACE MASKS, TYPE I (NOT FOR HEALTHCARE PROFESSIONALS)
T020604 - MEDICAL USE FACE MASKS, TYPE II AND IIR

The Notified Body hereby declares that the requirements of Annex XI, Part A of the REGULATION (EU) 2017/745 have been met for the listed products. The above named manufacturer has established and applies a production quality assurance, which is subject to periodic surveillance, defined by Annex XI, Part A, Section 7 of the aforementioned regulation. If class III devices or class IIb devices are covered by this certificate, an EU type-examination certificate in accordance with Annex X of the aforementioned regulation is required before placing them on the market.

Report No.: 190136114 120

Effective date: 2022-06-07

Expiry date: 2027-03-29

Issue date: 2022-06-07

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Wenxiang Zhang
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

Production Quality Assurance
REGULATION (EU) 2017/745 on Medical Devices, Annex XI, Part A

TÜVRheinland

Registration No.: DZ 2067318-1

Manufacturer: **Hubei V-Medical Products Co., Ltd.**
No. 67 Xianhong Road West, Xinlirenkou, Zhanggou Town, Xiantao City, 433012
Hubei, P.R. China

T030101 - COVER CAPS, INSTRUMENTS AND EQUIPMENT
V0102 - STAPLE REMOVER KNIVES, SINGLE-USE
V0199 - CUTTING DEVICES, SINGLE-USE - OTHER
V9012 - NON-SPECIALIST SURGICAL INSTRUMENTS AND KITS, SINGLE-USE
W050102 - URINE COLLECTION DEVICES
W050190 - SAMPLES COLLECTION DEVICES - VARIOUS

Authorised representative(s): **RAFFIN MEDICAL**
746 route de Sarcey 69490 Saint Romain De Popey France

Certificate history		
Revision:	Description:	Issue date:
0	Initial	2022-06-07

Report No.: 190136114 120

Effective date: 2022-06-07

Expiry date: 2027-03-29

Issue date: 2022-06-07

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Wenxiang Zhang
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.

Primeri

EU Quality Management System Certificate

Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
Certificate No. MDR-0010

Issued to:	JADRAN - GALENSKI LABORATORIJ d.d. Svilno 20, Croatia
SRN of the manufacturer:	HR-MF-000025715
EU authorised representative:	Not applicable
SRN of EU authorised representative:	Not applicable

SIQ has audited the quality management system in accordance with MDR Annex IX and found that the above-mentioned Manufacturer's quality management system meets the requirements of the Regulation (EU) 2017/745 concerning medical devices Annex IX. Devices covered by the Manufacturer's quality management system are listed on the page(s) below.

This certificate is based on:

Audit report No.:
OSV 00688B/2024, 2024-05-31
OSV 00610/2024, 2024-05-09
OSV 00428/2024, 2024-03-29
OSV 00189/2024, 2024-02-28
OSV 01511/2023, 2023-11-30
OSV 00994/2023, 2023-07-31
OSV 00124/2023, 2023-05-31
See also decision of NB`s commission for medical devices.

This certificate remains valid as long as the Manufacturer's quality management system is subject to periodical surveillance as referred to in Regulation (EU) 2017/745 concerning medical devices Annex IX and continues to meet the above requirements.

Reference to any previous certificate: /

Certification date:	2024-05-31
Issue:	MDR-0010/2024-05-31
Valid until:	2029-05-30

Managing Director of SIQ
Gregor Schoss

SIQ Ljubljana, Mašera-Spasićeva ulica 10, SI-1000 Ljubljana, Slovenia, Notified Body No. 1304
tel.: +386 1 4778 100 • fax: +386 1 4778 444 • e-mail: info@siq.si • http://www.siq.si

EU Quality Management System Certificate

Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
Certificate No. MDR-0010

Device:	Ophthalmology, Hyaluronic acid and derivates
EMDN:	Q02030301
Intended purpose:	Vizol S Lipid Balance eye drops are intended to alleviate symptoms of moderate to severe dry eye. They restore lipid layer of the tear film, stabilize tear file, and optimally moisturize the eye surface.
Classification:	IIb
Device:	Ophthalmology, Hyaluronic acid and derivates
EMDN:	Q02030301
Intended purpose:	Vizol S 0.21% drops for dry eyes are intended for relieving mild problems of dry eyes. Vizol S 0.4% drops for dry eyes are intended for relieving mild problems of dry eyes. Eye drops serve to protect, moisten, and lubricate eye. Drops application provides fast relief of discomfort.
Classification:	IIb
Device:	Ophthalmology, Hyaluronic acid and derivates
EMDN:	Q02030301
Intended purpose:	Vizol S INTENSIVE eye drops are designated to relieve mild to moderate dry eye problems, stabilise the tear film, lubricate the eye and smooth its surface. They also relieve disturbances in the case of: - Mechanical irritation of the eye surface (caused by wearing lenses, diagnostic or surgical interventions on the eye, - Mechanical irritation due to external factors (wind, sun, chlorinated water, pharmacotherapy), - eye strain (working for long periods on a computer).
Classification:	IIb

Specific conditions for or provisions or limitations to the validity of certificate:	/

Certification date:	2024-05-31
Issue:	MDR-0010/2024-05-31
Valid until:	2029-05-30

Managing Director of SIQ
Gregor Schoss

SIQ Ljubljana, Mašera-Spasićeva ulica 10, SI-1000 Ljubljana, Slovenia, Notified Body No. 1304
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SISTEM MENADŽMENTA KVALITETOM PO ISO 13485 I MDR (EU) 2017/745

- ISO 13485 je harmonizovani standard kojim proizvođači medicinskih sredstava dokazuju usaglašenost sistema menadžmenta kvalitetom sa zahtevima uredbe MDR

  Pored zahteva standarda proizvođači medicinskih sredstava moraju poštovati i primenjivati posebne zahteve koje propisuje MDR

  Pri postupku ocenjivanja usaglašenosti po Aneksu IX i Aneksu XI u delu A, preporučuje se da proizvođač ima uspostavljen sistem menadžmenta po standardu ISO 13485

IZVORI INFORMACIJA KOJI SU NAM DOSTUPNI

Nando baza - notifikovana tela
https://webgate.ec.europa.eu/single-market-compliance-space/#/notified-bodies/notified-body-list?filter=legislationId:34,notificationStatusId:1

- provera važnosti notifikacije, provera kodova koje obuhvata notifikacija

MDCG - smernice za primenu MDR
https://health.ec.europa.eu/medical-devices-sector/new-regulations/guidance-mdcg-endorsed-documents-and-other-guidance_en

KOJI SU NAM IZVORI INFORMACIJA DOSTUPNI

EUDAMED baza – pretraga po:

- *Economic operators* (manufacturers, system/procedure pack producers, authorised representatives, importers)
- *Devices, Systems, Procedure packs*
- *Certificates (issued or refused)*

https://ec.europa.eu/tools/eudamed/#/screen/home

REZIME

- ✓ Stavljanje u promet medicinskih sredstava u Evropskoj uniji zahteva CE oznaku koja pokazuje usklađenost sa propisima o medicinskim sredstvima
- ✓ CE oznaka znači da je proizvođač procenio medicinsko sredstvo i da ono ispunjava opšte zahteve za bezbednost i performanse prema MDR 2017/745
- ✓ Proizvođač će potvrditi usaglašenost sa svim relevantnim zahtevima EU i to mora navesti u svojoj Deklaraciji o usaglašenosti (DoC)
- ✓ Medicinska sredstva sa većim rizikom (klasa Is, Im, Ir, klasa IIa, klasa IIb i klasa III) zahtevaju nezavisnu procenu i sertifikaciju od strane notifikovanog tela
- ✓ Ovo rezultira EU sertifikatom koji izdaje notifikovano telo i potvrđuje usklađenost sistema menadžmenta kvalitetom (SMK) i tehničke dokumentacije proizvođača sa propisima EU

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