Digitally signed by Iurchevici Valeriu
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UE DECLARATION OF CONFORMITY

According to annexe IV of the regulation (UE) 2017/745 on medical devices

The manufacturer,

IDMED, S.A.S.

Hôtel Technoptic, 2 rue Marc Donadille
13013 – Marseille – France
Single Registration Number (SRN): FR-MF-000002402

Declares and certifies, under its sole responsibility, that the device:

TOFSCAN branded Idmed (NeuroMuscular Transmission Monitor), and its accessories (Basic UDI-DI: 36650230001LR)
&
TOFSCAN branded Draeger (NeuroMuscular Transmission Monitor), and its accessories (Basic UDI-DI: 36650230001LR)

with the following references are compliant with:

- the Directive 2017/2102 of the European Parliament and of the Council of 15 November 2017 and the Directive 2015/863 of 31 March 2015 amending Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS3)
- the General safety and performance requirements of the Regulation (UE) 2017/745
- the following harmonized standards:
- IEC 60601-1: 2012: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2: 2014: Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests
- IEC 60601-2-10: 2012: Medical electrical equipment – Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators
- IEC 60601-1-6: 2013 - Ed. 3.1 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- IEC 62304 :2006 Medical device software - Software life-cycle processes
- ISO 14971: 2019 Medical devices - Application of risk management to medical devices
- IEC 62366-1:2015-Ed. 1.1 Medical Devices - Part 1: Application Of Usability Engineering To Medical Devices
- ISO 10993-1: 2009: Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

REFERENCE	Branded	IUD-DI	DESCRIPTION
TOF-MU	Idmed	3665023000344	ToFscan NMT monitor
TOF-MU	Draeger	3665023000030	ToFscan NMT monitor
TOF-S2	_	3665023000047	Hand sensor and electrodes connector
TOF-S2_B	_	3665023000498	Hand sensor and electrodes connector
TOF-PS	_	3665023000054	Paediatric hand sensor and electrodes connector
TOF-PS_B	_	3665023000481	Paediatric hand sensor and electrodes connector
TOF-PS2_B	_	3665023000450	Small Paediatric hand sensor and electrodes connector
TOF-FS	_	3665023000061	Foot sensor and electrodes connector
TOF-FS_B	_	3665023000511	Foot sensor and electrodes connector
TOF-ES	_	3665023000078	Corrugator (eyebrow) sensor and electrodes connector
TOF-ES_B	_	3665023000504	Corrugator (eyebrow) sensor and electrodes connector
TOF-DS1	_	3665023000467	Disposable hand sensor with stimulation electrodes
TOF-CS1	_	3665023000474	Cable to connect disposable hand sensor to the ToFscan

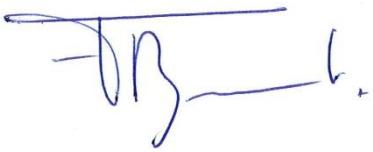
According to the annex VIII of the Regulation (UE) 2017/745, the device and its accessories are Class IIa rule 10.

The Intended purpose of the device and its accessories is to monitor the neuromuscular block of a patient in the operating theatre, recovery room or intensive care unit.

The declaration is based on following elements:

- Technical file DT_TOFSCAN attesting the compliance to the General safety and performance requirements of the Regulation (UE) 2017/745
- EC certificate n°38954 issued by the notified body n°0459, conformity assessment based on a quality management system and assessment of the technical documentation (annex IX chapters I & III and annex IX section 4).

Marseille, 2022/04/22



Frederic BERNERT – President

AGENȚIA MEDICAMENTULUI
ȘI DISPOZITIVELOR MEDICALE

REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

Введите текст для поиска...

Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data
			tofscan						
DM000422557	MONITOR DE TRANSMISIE NEUROMUSCULAR		TOFSCAN		Franta	IDMED S.A.S.	ECHIPAMED-PLUS S.R.L.	Rg04-000012	18-01-2023

CERTIFICAT UE DE SYSTEME DE GESTION DE LA QUALITE
Règlement (UE) 2017/745, Annexe IX Chapitres I et III

EU QUALITY MANAGEMENT SYSTEM CERTIFICATE
Regulation (EU) 2017/745, Annex IX Chapters I and III

Certificat/*Certificate:* N° 38954 rev. 0

Délivré le/*Issued on:* April 12th, 2022

Certificat délivré à/*Certificate issued to:* **IDMED**

Hôtel Technoptic 2 Rue Marc Donadille

13013 MARSEILLE FRANCE

SRN: FR-MF-000002402

GMED atteste qu'à l'examen des résultats figurant dans le(s) rapport(s) d'audit du système de gestion de la qualité référencé(s) P602976, P603947, le système de gestion de la qualité est conforme aux dispositions pertinentes du règlement (UE) 2017/745 pour les produits suivants :

GMED certifies that, on the basis of the results listed in the quality management system audit report(s) referenced P602976, P603947, the quality management system complies with the relevant provisions of the regulation (EU) 2017/745 for the following products:

Dispositifs médicaux de monitorage des paramètres physiologiques non vitaux dans le cadre de l'anesthésie et accessoires

Medical monitoring devices for non-vital physiological parameters in anesthesiology and accessories

Voir détails sur addendum / See addendum for additional information

Aux fins de la mise sur le marché de dispositifs de classe IIb implantables et/ou de classe III, un autre certificat délivré conformément aux dispositions du règlement (UE) 2017/745 est requis.

For the purpose of placing on the market implantable class IIb and / or class III devices, another certificate issued in accordance with the provisions of the regulation (EU) 2017/745 is required.

Début de validité /*Effective date:* April 12th, 2022 (included)

Valable jusqu'au /*Expiry date:* April 11th, 2027 (included)

La validité du présent certificat est conditionnée au respect des obligations qui découlent du système de gestion de la qualité approuvé et de la surveillance effectuée par l'organisme notifié prévue par le règlement. Ce certificat est lié par les conditions du contrat.

The validity of this certificate is subject to compliance with the obligations arising from the approved quality management system and from the surveillance carried out by the notified body as required by the regulation. This certificate is bound by the conditions of the contract.

DocuSigned by:
Lionel DREUX
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Lionel DREUX
Certification Director

720 RDM 0701-75 rev 2

GMED • Société par Actions Simplifiée au capital de 300 000 € • RCS Paris 839 022 522 • Organisme Notifié/Notified Body n° 0459
Siège social : 1, rue Gaston Boissier - 75015 Paris • Tél. : 01 40 43 37 00 • lne-gmed.com

1. Identification des sites / *Identification of sites:*

IDMED
Hôtel Technoptic, 2 rue Marc Donadille, 13013 MARSEILLE, FRANCE

IDMED
3 rue John Maynard Keynes, 13013 MARSEILLE, FRANCE

2. Identification des dispositifs / *Identification of devices:*

Nom du dispositif médical *Medical device name*	**Nom commercial** *Commercial name*	**Classe du DM** *MD Class*
TOF-MU	**ToFscan (branded Idmed)**	**IIa**
TOF-MU	**ToFscan (branded Draeger)**	
TOF-S2	**ToFscan**	
TOF-S2_B	**ToFscan**	
TOF-PS	**ToFscan**	
TOF-PS_B	**ToFscan**	
TOF-PS2_B	**ToFscan**	
TOF-FS	**ToFscan**	
TOF-FS_B	**ToFscan**	
TOF-ES	**ToFscan**	
TOF-ES_B	**ToFscan**	
TOF-DS1	**ToFscan**	
TOF-CS1	**ToFscan**	
NL-MU	**NeuroLight**	

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Lionel DREUX
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Lionel DREUX
Certification Director

Nom du dispositif médical *Medical device name*	**Nom commercial** *Commercial name*	**Classe du DM** *MD Class*
ALG-MU	**AlgiScan**	**IIa**
CAB-STIM3	**AlgiScan**	
WiTOF-MU	**WiTOF**	
WiTOF-S	**WiTOF**	
WiTOF-FS	**WiTOF**	

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Lionel DREUX
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Lionel DREUX
Certification Director