MEDSORB DOMINICANA, S.A. Registrada ISO 13485

DECLARATION OF CONFORMITY

Document Name	TFMD0405
Manufacturer Name	Medsorb Dominicana, S.A.
Product Brand	Ivalon® by FABCO®
Product Name	General Surgical
Intended Purpose	Instrument Wipes are used in cleaning debris from delicate surgical instruments. PVA Knife Cleaning Blocks are used in cleaning debris from delicate surgical blades/knives.
SRN (Single Registration Number)	DO-MF-000030902
Authorized Representative	MDSS GmbH
Authorized Representative Addresses	Schiffgraben 41 30175 Hannover Germany
Authorized Representative SRN (Single Registration Number)	DE-AR-000005430
Basic UDI-DI	See Appendix A

We, the manufacturer hereby declare under our own responsibility that the QMS is in compliance with the EU Regulation 2017/745. Conformity route applied was Production Quality Assurance, Annex XI Part A and Article 10 of the MDR.

Product Code	See Appendix A
Risk Class	Class Is, according to Annex VIII, Rule 5
Notify Body Name	GMED SAS
NB Addresses	1 Rue Gaston 75015 Paris, France
Notify Body Number	0459
EC Certificate	39397 rev. 1 (Appendix B)
Date of Issue Certificate	September 20th, 2023
Date of Expire Certificate	August 31st, 2028

06/07/2024	Eddyth M. Florentino	[signature]	06/07/2024	SPM / Dominican Republic
DOC Date of Issuance (MM/DD/YYYY)	Medsorb Regulatory Management	Signature	Date signed (MM/DD/YYYY)	Location (City/Country)
06/07/2024	Belkis Natta	[signature]	06/07/2024	SPM / Dominican Republic
DOC Date of Issuance (MM/DD/YYYY)	Medsorb Quality Management	Signature	Date signed (MM/DD/YYYY)	Location (City/Country)

www.medsorb.net
MEDSORB DOMINICANA, S.A. Zona Franca Industrial, San Pedro de Macorís, República Dominicana
3 State Pier Rd., New London, CT 06320
Tel: (809) 529-6167 Fax: (809) 529-2585
Tel: (860) 442-4914 Fax: (860) 442-5895

DECLARATION OF CONFORMITY

Appendix A

The following listed models are complaint to the requirements stated on page 1

Product Code	Description	BASIC UDI-DI
Q604201	Instrument Wipe, 1mm, 8.25 cm x 8.25 cm x 1mm	0634303IVALONWIPEWN
Q604202	Instrument Wipe, 2mm, 8.25 cm x 8.25 cm x 2mm	0634303IVALONWIPEWN
Q604232	PVA knife Cleaning Block	0634303IVALONKNIFEBLOCK86

DECLARATION OF CONFORMITY

Appendix B

CERTIFICAT UE D'ASSURANCE QUALITE DE LA PRODUCTION
Règlement (UE) 2017/745, Annexe XI Partie A
EU PRODUCTION QUALITY ASSURANCE CERTIFICATE
Regulation (EU) 2017/745, Annex XI Part A

Certificat/*Certificate:* N° 39397 rev. 1

Délivré le */Issued on:* September 20th, 2023

Certificat délivré à */Certificate issued to:* **Medsorb Dominicana S.A.**
Zona Franca Industrial
San Pedro de Macoris - DOMINICAN REPUBLIC
SRN: DO-MF-000030902

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) T001280_P4-DOCA, le système de gestion de la qualité (production) est conforme aux dispositions pertinentes du règlement (UE) 2017/745, limité aux aspects liés à l'obtention, à la préservation et au maintien de l'état stérile pour les produits suivants :

GMED certifies that, on the basis of the results listed in the quality management system audit report(s) referenced T001280_P4-DOCA, the quality management system (production) complies with the relevant provisions of the regulation (EU) 2017/745, limited to the aspects concerned with establishing, securing and maintaining sterile conditions for the following products:

Eponges ophtalmiques - Eponges nasales - Eponges auriculaires - Lingettes pour instruments - Blocs de nettoyage PVA pour bistouris

Ophthalmic sponges - Nasal sponges - Ear sponges - Instrument wipes - PVA Knife Cleaning Blocks

Voir détails sur addendum / See addendum for additional information

Début de validité */Effective date:* September 1st, 2023 (included)
Valable jusqu'au */Expiry date:* August 31st, 2028 (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.

On behalf of the President
Béatrice LYS
Technical Director

GMED - 39397 rev. 1
Annule et remplace le certificat 39397-0

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 • ine-gmed.com