DECLARACIÓN UE CONFORMIDAD

Distribuidor: JBM CAMPLLONG, S.L.U.

Dirección: CIM La Selva – Crta. Aeroport Km 1.6 Nave 2.2, 17185 Vilobí d'Onyar, Girona

CIF: ESB17419292

Descripción del producto: BOTIQUÍN DE PRIMEROS AUXILIOS DIN13157

Referencia del distribuidor: 54072

El objeto de la declaración es conforme a las Directivas 2017/745 sobre los productos sanitarios; y a los siguientes estándares:

Firmado:

JBM CAMPLLONG, S.L.U.
CIM LA SELVA - Ctra. de l'Aeroport Km. 1,6 Nau 2.2
17185 VILOBÍ D'ONYAR
GIRONA - SPAIN
Tel. 972 24 55 33 - Fax +34 972 24 54 37

Eduard Godoy

Director departamento de compras

En Girona, a 28 de abril de 2022

By Royal Charter

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 732347 R000

Manufacturer:

Single Registration Number: Not Available

EU Authorised Representative: MedPath GmbH

Address:
Mies-van-der-Rohe-Strasse 8
80807 Munich
Germany

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III and Class IIb implantable devices an Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2021-02-22** Date: **2021-07-30** Expiry Date: **2026-02-21**

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EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

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Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Disposable Medical Mask	Class Is
First Aid Dressing Bandage	Class Is
Absorbent Non-Woven Compress	Class Is
First Aid Kit (containing various sizes of First Aid Dressing Bandage & Absorbent Non-Woven Compress)	Class Is

For Class Is devices, the Notified Body conformity assessment is limited to the aspects relating to establishing, securing and maintaining sterile conditions.

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EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 732347 R000

Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference number	Action
22 February 2021	3255769	First Issue.
Current	3477389	Amended – change of manufacturer address to No. 82 TuanFeng Avenue. Supplemented – addition of First Aid Dressing Bandage, Absorbent Non-Woven Compress & First Aid Kit.

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
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