EU DECLARATION OF CONFORMITY

Distributed by: JBM CAMPLLONG, S.L.U.

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

CIF (VAT number): ESB17419292

Product's description: FIRST AID KIT DIN13157

Distributor's reference: 54072

The declaration object complies with the Directives 2017/745 (sanitary products); and the following standards:

Signed:

Eduard Godoy

Purchasing department director

Girona, 28th of April, 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

MDR 732347 R000

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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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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