



EC Declaration of Conformity to: Medical Devices Directive 93/42/EEC

Legal Manufacturer:	Caesarea Medical Electronics Ltd. 16 Shacham Street Industrial Park Caesarea North PO Box 3009, Caesarea 3088900, Israel
Authorized European Representative:	Becton Dickinson Ireland Ltd. Donore Road, Drogheda, Co. Louth, A92 YW26, Ireland
Manufacturing Site(s):	16 Shacham Street Industrial Park Caesarea North PO Box 3009, Caesarea 3088900, Israel <u>Additional Locations:</u> 9 Leshem Street, Industrial Park Caesarea, 3088900 Caesarea, Israel 1 Leshem Street, Industrial Park Caesarea, 3088900 Caesarea, Israel 13 Shacham Street Industrial Park Caesarea, 3088900 Caesarea, Israel
Device Description/Family:	BodyGuard™ MultiPurpose Infusion Pump System (See below Product Schedule)
EC Product Classification:	Class IIb, Annex IX, Rule 11
GMDN:	13215 – General-purpose infusion pump, line-powered A mains electricity (AC-powered) device designed to facilitate the accurate and consistent administration of drugs and solutions which can be delivered via intravenous, subcutaneous, arterial, epidural, and intracavitary routes using a dedicated infusion set. It is used to supply higher pressures than those provided by manually clamped gravity infusion sets or infusion controllers. The device has a typical flow range of 1 to 999 ml/hour and delivers solutions from a standard infusion bag or bottle of fluid. It typically has internal batteries that enable operation for a short period when no mains electricity is available (e.g., during transportation or a power outage).

We herewith declare, as the sole manufacturer, that the product(s) listed above and detailed in the attached Product Schedule meet the provisions of the Council Directive 93/42/EEC of 14 June 1993 as amended, concerning medical devices.

Applied Directives:	<ul style="list-style-type: none">- Medical Device Directive 93/42/EEC- *Directive 2011/65/EU including Directive (EU) 2015/863 (RoHS 3)- *Waste electrical and electronic equipment 2012/19/EU <i>*not part of conformity assessment issued by Notified Body DEKRA Certification B.V.</i>
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Applied Standards	<ul style="list-style-type: none"> - ISO 13485: 2016 - ISO 14971: 2019 - IEC 60601-1: 2005+AMD1:2012 - IEC 60601-1-2: 2014 - IEC 60601-1-6: 2010+AMD1:2013 - IEC 60601-1-8: 2006+AMD1:2012 - IEC 60601-1-11: 2015 - IEC 60601-1-12: 2014 - IEC 60601-2-24: 2012 - IEC 62304: 2006+AMD1:2015 - IEC 62366-1: 2015 - ISO 15223-1: 2021 - IEC 60529: 1991/A2:2013 - ISTA-2A:2011
Notified Body:	DEKRA Certification B.V. Meander 1051, 6825MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands Notified Body Number: 0344
CE Certificate Number:	Annex II (EC Certificate No.2122031CE01, Revision date 23-Mar-2020)
Date of issuance of original CE certificate:	5 June 2009

STED File: D04330 Rev. 11
DoC File: D04332 Rev. 10

Signed: Ondina Bennaim

Ondina Bennaim

Date: 31 October 2022

Senior Director Regulatory Affairs
International Infusion – MMS



Product Schedule

BodyGuard™ Multipurpose Infusion Pump System

Part Number	Description	Product Class	GMDN	1st SN
999-603EN	BodyGuard™ 323 Color Vision Infusion Pump English	IIb	13215	V119609
999-603BDEN	BD BodyGuard™ Infusion Pump English	IIb	13215	As above
999-603ES	BodyGuard™ 323 Color Vision Infusion Pump Spanish	IIb	13215	As above
999-603BDES	BD BodyGuard™ Infusion Pump Spanish	IIb	13215	As above
999-603IT	BD BodyGuard™ Infusion Pump Italian	IIb	13215	As above
999-603DE	BD BodyGuard™ Infusion Pump German	IIb	13215	As above
999-603FR	BD BodyGuard™ Infusion Pump French	IIb	13215	As above
999-603NL	BD BodyGuard™ Infusion Pump Dutch	IIb	13215	As above
999-603DK	BD BodyGuard™ Infusion Pump Danish	IIb	13215	As above
999-603SE	BD BodyGuard™ Infusion Pump Swedish	IIb	13215	As above
999-603FI	BD BodyGuard™ Infusion Pump Finnish	IIb	13215	As above
999-603NO	BD BodyGuard™ Infusion Pump Norwegian	IIb	13215	As above
999-603PT	BD BodyGuard™ Infusion Pump Portuguese	IIb	13215	As above
999-603GR	BD BodyGuard™ Infusion Pump Greek	IIb	13215	As above
999-603PL	BD BodyGuard™ Infusion Pump Polish	IIb	13215	As above
999-603TU	BD BodyGuard™ Infusion Pump Turkish	IIb	13215	As above
999-603PFM	BD BodyGuard™ Infusion Pump German (PFM)	IIb	13215	V500000

Other Items:

Part Number	Description	GMDN
140-100X	Bolus cable without light	37274
140-400X	Bolus cable with light	37274
130-050XV	Rechargeable Li-polymer battery, 1800 mAh	37274
130-051XV	Rechargeable Li-polymer battery, 3600 mAh	37274
999-WC	Wall charger 8.4V	37274
PCG00020	BD BodyGuard™ charger	37274
170-250X	BD BodyGuard™ small Lockbox	37274
190-900PXCVI	BD BodyGuard™ Ultimate Lockbox	37274
190-960XCV	Key for BD BodyGuard™ Ultimate lockbox	37274
121-100X	BD BodyGuard™ Drop sensor	37274
CNC00002	BD BodyGuard™ Pole clamp adaptor	37274
150-000X	100ml BD BodyGuard™ Pouch Blue	37274
150-001X	500ml BD BodyGuard™ Pouch Blue	37274
150-250XD	250ml BD BodyGuard™ Pouch Disposable	37274
150-250XE	250ml BD BodyGuard™ Pouch Yellow	37274
160-002XB	2L BD BodyGuard™ Bag Black	37274
160-002XG	2L BD BodyGuard™ Bag Grey	37274
160-002XP	2L BD BodyGuard™ Bag Pink	37274
BAG00008	3L BD BodyGuard™ Bag	37274
CASE0002	Universal carrying case	37274
CNC00001	Universal trolley	37274
100-071	Power Cord 2.5m (Connector type IS)	37274
100-071XA	Power Cord 2.5m (Connector type EU)	37274
100-072XA	Power Cord 1.8m (Connector type UK)	37274
Part Number	Description	GMDN
BODYCOMM-3.2	BodyComm™ Kit	37274
197-100X	BodyComm™ Cable	37274

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