

EU DECLARATION OF CONFORMITY (DoC)

Manufacturer:	Sendal S.L. Ctra. Nacional Madrid-Cáceres s/n 10350 Almaraz, Cáceres SPAIN
Manufacturer SRN:	ES-MF-000016981.
Authorised Representative:	The manufacturer is located in the Union therefore an Authorised Representative is not required.
Authorised Representative SRN:	The manufacturer is located in the Union therefore an Authorised Representative is not required.
Product:	BD Pressure Rated Extension Sets.
Basic UDI-DI:	BD Pressure Rated Extension Sets: 8428820BDAADMINEXTSETY6. BD Pressure Rated Catheter Extension Sets: 8428820BDCADMINEXTSET2K. BD Pressure Rated Extension Sets with Stopcock: 8428820BD3ADMINEXTSETH5. BD PCA Administration Extension Sets: 8428820BDPADMINEXTSETHL.
Risk Class and Rule:	Class IIa, Annex VIII, Rule 2.
Intended Purpose	<p>BD Pressure Rated Extension Sets: BD Pressure Rated Extension Sets are sterile, single use devices intended to be attached to the IV line or catheter to lengthen and/or provide additional IV access ports. Pressure Rated Extension Sets can be used for direct injection, intermittent infusion, and/or continuous infusion of fluids and/or medications.</p> <p>BD Pressure Rated Catheter Extension Sets: BD Pressure Rated Catheter extension sets are sterile, single use devices intended to be attached to an IV catheter to decrease movement /manipulation of the catheter hub and provide extra length, and functionality. Pressure Rated Catheter Extension Sets can be used for direct injection, intermittent infusion, and/or continuous infusion of fluids and/or medications.</p> <p>BD Pressure Rated Extension Sets with Stopcock: BD Pressure Rated Extension Sets with Stopcock are sterile, single use devices intended to be attached to an IV catheter. Pressure Rated Extension Sets with Stopcock can be used for direct injection, intermittent infusion, and/or continuous infusion of fluids and/or medications through multiple ports controlled by rotating the lever/handle to direct the fluid path.</p> <p>BD PCA Administration Extension Sets: BD PCA Administration Extension Sets are sterile, single use devices intended to be attached to an IV-line, catheter and/or syringe to facilitate the delivery of fluids and/or patient controlled analgesic medication via pump intravenous administration. PCA Administration Extension Sets can be used for direct injection, intermittent infusion, and/or continuous infusion of fluids and/or medications.</p>
Notified Body:	TÜV SÜD Product Service GmbH Ridlerstraße 65, 80339 Munich, Germany Notified Body Number: 0123
<p>We, as the manufacturer of the device(s) take sole responsibility for and hereby declare that the above mentioned product(s) meet(s) the provisions of the following Directives/ Regulation(s):</p> <ul style="list-style-type: none"> Regulation (EU) 2017/745 of the European Parliament and of the Council on Medical Devices 	

Conformity Assessment Route:

☒ ANNEX IX Chapter I and III – Quality management System

EC CERTIFICATE No.: G10 064670 0026

Certificate Expiration Date: 23 October 2027

Common Specifications (CS):

Common Specifications have not been issued for this product.


Devices Covered by this DoC:

SKU#	Device Name	Device Class	EMDN Code
FN-12	BD Pressure Rated Extension Sets	IIa	A030201
PA-100	BD Pressure Rated Extension Sets	IIa	A03020102
PA-150	BD Pressure Rated Extension Sets	IIa	A03020102
PA-200	BD Pressure Rated Extension Sets	IIa	A03020102
PA-50	BD Pressure Rated Extension Sets	IIa	A03020102
PA-100-G	BD Pressure Rated Extension Sets	IIa	A03020102
PA-50-G	BD Pressure Rated Extension Sets	IIa	A03020102
PA-150-G	BD Pressure Rated Extension Sets	IIa	A03020102
PA-150-CV	BD Pressure Rated Extension Sets	IIa	A03020102
PA-200-G	BD Pressure Rated Extension Sets	IIa	A03020102
PA-250-G	BD Pressure Rated Extension Sets	IIa	A03020102
PA-80-GC	BD Pressure Rated Extension Sets	IIa	A03020102
PA-150-GC	BD Pressure Rated Extension Sets	IIa	A03020102
PA-200-GC	BD Pressure Rated Extension Sets	IIa	A03020102
PA-150-OP	BD Pressure Rated Extension Sets	IIa	A03020102
PA-200-OPG	BD Pressure Rated Extension Sets	IIa	A03020102
PA-150-OPG	BD Pressure Rated Extension Sets	IIa	A03020102
PA-100-V	BD Pressure Rated Extension Sets	IIa	A03020102
PA-150-V	BD Pressure Rated Extension Sets	IIa	A03020102
PA-200-V	BD Pressure Rated Extension Sets	IIa	A03020102
PA-200-L	BD Pressure Rated Extension Sets	IIa	A03020102
PA-200-MM	BD Pressure Rated Extension Sets	IIa	A03020102
PA-CT	BD Pressure Rated Extension Sets	IIa	A030201
DP-100	BD Pressure Rated Extension Sets	IIa	A03020102
DP-150	BD Pressure Rated Extension Sets	IIa	A03020102
DP-200	BD Pressure Rated Extension Sets	IIa	A03020102
DP-150-OP	BD Pressure Rated Extension Sets	IIa	A03020102
DP-150-V	BD Pressure Rated Extension Sets	IIa	A03020102
DP-140-SP	BD Pressure Rated Extension Sets	IIa	A03020102
DP-140-SPV	BD Pressure Rated Extension Sets	IIa	A03020102

DH-100	BD Pressure Rated Extension Sets	IIa	A03020102
DH-150	BD Pressure Rated Extension Sets	IIa	A03020102
DH-200	BD Pressure Rated Extension Sets	IIa	A03020102
DH-50	BD Pressure Rated Extension Sets	IIa	A03020102
DH-80	BD Pressure Rated Extension Sets	IIa	A03020102
DH-150-A	BD Pressure Rated Extension Sets	IIa	A03020102
DH-60-V	BD Pressure Rated Extension Sets	IIa	A03020102
DH-150-V	BD Pressure Rated Extension Sets	IIa	A03020102
DH-200-V	BD Pressure Rated Extension Sets	IIa	A03020102
DH-150-DV	BD Pressure Rated Extension Sets	IIa	A03020102
DI-100-G	BD Pressure Rated Extension Sets	IIa	A030201
DI-200-G	BD Pressure Rated Extension Sets	IIa	A030201
DI-50-G	BD Pressure Rated Extension Sets	IIa	A030201
DI-2	BD Pressure Rated Extension Sets	IIa	A030201
DI-2/CHT	BD Pressure Rated Extension Sets	IIa	A030201
FN-02-LD	BD Pressure Rated Extension Sets	IIa	A030201
F-012	BD Pressure Rated Extension Sets	IIa	A030201
F-022	BD Pressure Rated Extension Sets	IIa	A030201
F-022-G	BD Pressure Rated Extension Sets	IIa	A030201
F-022-LD	BD Pressure Rated Extension Sets	IIa	A030201
F-525	BD Pressure Rated Extension Sets	IIa	A030201
FN-02	BD Pressure Rated Extension Sets	IIa	A030201
FN-12S	BD Pressure Rated Extension Sets	IIa	A030201
CON-MM	BD Pressure Rated Catheter Extension Sets	IIa	A030201
DH-10	BD Pressure Rated Catheter Extension Sets	IIa	A03020102
DH-25	BD Pressure Rated Catheter Extension Sets	IIa	A03020102
DH-25-V	BD Pressure Rated Catheter Extension Sets	IIa	A03020102
DI-10-GC	BD Pressure Rated Catheter Extension Sets	IIa	A030201
DI-15-GC	BD Pressure Rated Catheter Extension Sets	IIa	A030201
DI-25	BD Pressure Rated Catheter Extension Sets	IIa	A030201
DI-25-G	BD Pressure Rated Catheter Extension Sets	IIa	A030201
DP-30	BD Pressure Rated Catheter Extension Sets	IIa	A03020102
20019E7DS	BD Pressure Rated Catheter Extension Sets	IIa	A03020102
20038E7DS	BD Pressure Rated Catheter Extension Sets	IIa	A03020102
20039E7DS	BD Pressure Rated Catheter Extension Sets	IIa	A03020102
PA-15	BD Pressure Rated Catheter Extension Sets	IIa	A03020102
PA-10-G	BD Pressure Rated Catheter Extension Sets	IIa	A03020102
PA-25-G	BD Pressure Rated Catheter Extension Sets	IIa	A03020102
TPS-01-05	BD Pressure Rated Catheter Extension Sets	IIa	A030201
TPS-01-10	BD Pressure Rated Catheter Extension Sets	IIa	A030201
TPS-09-10	BD Pressure Rated Catheter Extension Sets	IIa	A030201
TPS-22	BD Pressure Rated Catheter Extension Sets	IIa	A030201
TPS-22-UK	BD Pressure Rated Catheter Extension Sets	IIa	A030201
TPS-22-UKV	BD Pressure Rated Catheter Extension Sets	IIa	A030201

TPS-23	BD Pressure Rated Catheter Extension Sets	Ila	A030201
TPS-23-UKV	BD Pressure Rated Catheter Extension Sets	Ila	A030201
2239ES	BD Pressure Rated Catheter Extension Sets	Ila	A030201
2241ES	BD Pressure Rated Catheter Extension Sets	Ila	A030201
2245ES	BD Pressure Rated Catheter Extension Sets	Ila	A030201
2275ES	BD Pressure Rated Catheter Extension Sets	Ila	A030201
BW-120-3VG	BD Pressure Rated Extension Sets with Stopcock	Ila	A030201
DH-100-3V	BD Pressure Rated Extension Sets with Stopcock	Ila	A03020102
DH-10-3V	BD Pressure Rated Extension Sets with Stopcock	Ila	A03020102
DH-25-3V	BD Pressure Rated Extension Sets with Stopcock	Ila	A03020102
DH-50-3V	BD Pressure Rated Extension Sets with Stopcock	Ila	A03020102
DH-100-3VTP	BD Pressure Rated Extension Sets with Stopcock	Ila	A03020102
DI-100-3VG	BD Pressure Rated Extension Sets with Stopcock	Ila	A030201
DI-10-3VG	BD Pressure Rated Extension Sets with Stopcock	Ila	A030201
DI-150-3VG	BD Pressure Rated Extension Sets with Stopcock	Ila	A030201
DI-25-3VG	BD Pressure Rated Extension Sets with Stopcock	Ila	A030201
DI-50-3VG	BD Pressure Rated Extension Sets with Stopcock	Ila	A030201
DI-80-3VG	BD Pressure Rated Extension Sets with Stopcock	Ila	A030201
DI-15-3V3	BD Pressure Rated Extension Sets with Stopcock	Ila	A030201
L-303/10-PA	BD Pressure Rated Extension Sets with Stopcock	Ila	A03020102
L-303/25-PA	BD Pressure Rated Extension Sets with Stopcock	Ila	A03020102
L-305/10-TPS	BD Pressure Rated Extension Sets with Stopcock	Ila	A030201
PCA-01	BD PCA Administration Extension Sets	Ila	A03020102
PCA-04	BD PCA Administration Extension Sets	Ila	A03020102

Authorised Signatory:

Name & Title:	Juan Antonio Ordiales, PRRC for Sendal S.L.
On behalf of:	Sendal S.L.
Place:	Ctra. Nacional Madrid-Cáceres s/n 10350 Almaraz, Cáceres SPAIN
Date:	01 Dec 2023
Signature:	

**BD**

BD | Almaraz (Sendal)

Document No. STED-03

Revision/Version: 04

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DECLARATION OF CONFORMITY Revision History:

Revision:	Detailed Change Description:
01	Document First Release (ECR: 500000290366)
02	Include references from project MPS-609, review applicable standards (ECO: 500000306633)
03	Include reference CON-MM (ECO:500000318998)
04	Include references for MPS-533A Phase V and typo (ECO: 500000336057)

