

## EU DECLARATION OF CONFORMITY (DoC)

<b>Manufacturer:</b>	Sendal S.L. Ctra. Nacional Madrid-Cáceres s/n 10350 Almaraz, Cáceres SPAIN
<b>Manufacturer SRN:</b>	ES-MF-000016981
<b>Authorised Representative:</b>	The manufacturer is located in the Union therefore an Authorised Representative is not required.
<b>Authorised Representative SRN:</b>	The manufacturer is located in the Union therefore an Authorised Representative is not required.
<b>Product:</b>	BD Gravity IV Sets, Vial/Bag Access Devices, and Accessories
<b>Basic UDI-DI:</b>	<b>8402882BDPGRAVITYADMIN7J:</b> BD Primary Gravity Sets <b>8402882BDF3GRAVITYADMINBM:</b> BD Primary Gravity Sets with Stopcocks <b>8402882BDF3GRAVITYADMINBM:</b> BD Primary / Extension Sets with Flow Regulators <b>8402882BDF3GRAVITYADMINBM:</b> BD Secondary Sets <b>8402882BDFVGRAVITYADMINPA:</b> BD Standalone Vial / Bag Access Devices
<b>Risk Class and Rule:</b>	Class I, Annex VIII, Rule 2
<b>Intended Purpose</b>	<p><b>BD Primary Gravity Sets:</b> BD Primary Gravity Sets are sterile, single use devices that attach to the IV line for infusion therapy by gravity feed. BD Primary Gravity Sets can be used for direct injection, intermittent infusion, and/or continuous infusion of fluids and/or medications.</p> <p><b>BD Primary Gravity Sets with Stopcocks:</b> BD Primary Gravity Sets with Stopcocks are sterile, single use devices intended to be attached to an IV catheter. BD Primary Gravity Sets with Stopcocks can be used for direct injection, intermittent infusion, and/or continuous infusion of fluids and/or medications through multiple ports controlled by rotating the handle / lever to direct the fluid path by gravity feed.</p> <p><b>BD Primary / Extension Sets with Flow Regulators:</b> BD Primary / Extension Sets with Flow Regulators are sterile, single use devices that attach to the IV line or catheter to lengthen and/or provide functionality and additional IV access ports. BD IV Extension Sets with Flow Regulators can be used for direct injection, intermittent infusion, and/or continuous infusion of fluids and/or medications by rotating the dial manually to control the rate of infusion per hour by gravity feed.</p> <p><b>BD Secondary Sets:</b> BD Secondary Sets (IV Piggyback sets) are sterile, single-use, short infusion sets that attach to the upper IV access port of a primary administration set for intermittent infusion, and/or continuous infusion of fluids and/or medications by gravity feed.</p> <p><b>BD Standalone Vial/Bag Access Devices:</b> BD standalone vial/bag access devices are sterile, single-use transfer devices that provides access to a single IV bag or container for transfer of fluids or medications to another IV bag(s) or container(s).</p>

**Notified Body:**

TÜV SÜD Product Service GmbH  
Ridlerstraße 65, 80339 Munich, Germany  
Notified Body Number: 0123

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):

- 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.: G11 064670 0027

Certificate Expiration Date: 23 October 2027

**Common Specifications (CS):**

Common Specifications have not been issued for this product.

**Devices Covered by this DoC:**

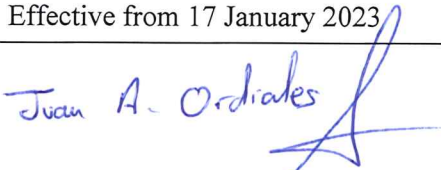
SKU#	Device Name	Device Class	EMDN Code
TPS-200	BD Primary Gravity Sets	Is	A030401
A96	BD Primary Gravity Sets	Is	A030401
NT-35-PRIV	BD Primary Gravity Sets	Is	A030401
A64-3VTPS	BD Primary Gravity Sets with Stopcocks	Is	A030401
A64-3VDH60	BD Primary Gravity Sets with Stopcocks	Is	A030401
NT-82-LLEV20P	BD Primary Gravity Sets with Stopcocks	Is	A030401
A34-3V-CM	BD Primary Gravity Sets with Stopcocks	Is	A030401
RGA65-23V	BD Primary Gravity Sets with Stopcocks	Is	A030401
NT-33-3VP	BD Primary Gravity Sets with Stopcocks	Is	A030401
A65-23V	BD Primary Gravity Sets with Stopcocks	Is	A030401
NT-85-3VLM	BD Primary Gravity Sets with Stopcocks	Is	A030401
A64-MS	BD Primary Gravity Sets with Stopcocks	Is	A030401
NT-33V-3VP	BD Primary Gravity Sets with Stopcocks	Is	A030401
A34-3V-LR	BD Primary Gravity Sets with Stopcocks	Is	A030401
A64-3VRN	BD Primary Gravity Sets with Stopcocks	Is	A030401
NT-82-LLEV10	BD Primary Gravity Sets with Stopcocks	Is	A030401
NT-82-LLEV25	BD Primary Gravity Sets with Stopcocks	Is	A030401
NT-82-LLEV50	BD Primary Gravity Sets with Stopcocks	Is	A030401
B642-3V15	BD Primary Gravity Sets with Stopcocks	Is	A030401
NT-82-LLEV75	BD Primary Gravity Sets with Stopcocks	Is	A030401
RG-SY-20	BD Primary/Extension Sets with Flow Regulators	Is	A03010103
RG-3-C	BD Primary/Extension Sets with Flow Regulators	Is	A03010103
RG-3-CSY	BD Primary/Extension Sets with Flow Regulators	Is	A03010103
RG-1	BD Primary/Extension Sets with Flow Regulators	Is	A03010103





SKU#	Device Name	Device Class	EMDN Code
RG-SY	BD Primary/Extension Sets with Flow Regulators	Is	A03010103
CYTO20-FSV	BD Secondary Sets	Is	A030401
CYTO12-F	BD Secondary Sets	Is	A030401
CYTO16/2	BD Secondary Sets	Is	A030401
NT-82-ELL50C	BD Secondary Sets	Is	A030401
CYTO20	BD Secondary Sets	Is	A030401
CYTO20-SV	BD Secondary Sets	Is	A030401
CYTO20-SVOP	BD Secondary Sets	Is	A030401
CYTO12	BD Secondary Sets	Is	A030401
CYTO17-OP	BD Secondary Sets	Is	A030401
TPS-51	BD Standalone Vial / Bag Access	Is	A070103
TR-31	BD Standalone Vial / Bag Access	Is	A070103
PF-01	BD Standalone Vial / Bag Access	Is	A070103
PF-310	BD Standalone Vial / Bag Access	Is	A070103
TPS-51-UK	BD Standalone Vial / Bag Access	Is	A070103

**Authorised Signatory:**

<b>Name &amp; Title:</b>	Juan Antonio Ordiales, PRRC for Sendal S.L.
<b>On behalf of:</b>	Sendal S.L
<b>Place of Issue:</b>	Ctra. Nacional Madrid-Cáceres s/n 10350 Almaraz, Cáceres SPAIN
<b>Date of Issue:</b>	Effective from 17 January 2023
<b>Signature:</b>	

**DECLARATION OF CONFORMITY Revision History:**

Revision:	Detailed Change Description:
01	Document First Release (ECR: 500000297971)
02	Correct Number CE Cert (ECR: 500000300725)

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