

# Technical Data Sheet

<b>Manufacturers Name:</b>	Blue Medical B.V.
<b>Manufacturers Address:</b>	Sluispolderweg 79, 1505HJ, Zaandam, The Netherlands
<b>SRN (Single Registration Number):</b>	NL-MF-000010818
<b>Name of the Device (s):</b>	<b>CP   B&amp;D Type Autoclave Test Pack</b>
<b>Product group code (s):</b>	BM33001020
<b>Classification:</b>	Non-Medical Device
<b>Manufacturer product category:</b>	CP
<b>Manufacturer product group:</b>	CP   B&D Type Autoclave Test Pack
<b>Market product category:</b>	Chemical indicators
<b>Product color:</b>	Process indicator (Type 1) on back of the test pack turns from pink to black. Indicator sheet (Type 2) in the pack turns from blue to pink.
<b>Product size:</b>	100mm x 75mm
<b>Applicable standards:</b>	ISO-11140-1:2014 (Type 2) / ISO-11140-4:2007
<b>Suitable processes:</b>	STEAM
<b>Stated Values (SV):</b>	134°C – 137°C for 3,3 min. to 3,5 min.
<b>Instructions for use:</b>	YES, eIFU <a href="http://www.blue-medical.nl/eifu">www.blue-medical.nl/eifu</a>
<b>HS / Customs code:</b>	3822.9000
<b>Shelf life:</b>	4 years
<b>Lead free:</b>	YES
<b>Latex free:</b>	YES
<b>DEHP / CMR free:</b>	YES

**Storage conditions:** Humidity limitation 30% - 70% / Temperature limit +10°C - +30°C / Keep dry / Keep away from sunlight

**Product symbol markings:** Do not re-use / Do not use if package is damaged / Catalogue number (REF) / Batch code (LOT) / Consult instructions for use / Date of manufacture / Humidity limitation / Keep away from sunlight / Manufacturer / STEAM / Temperature limit / Use-by date / Keep dry

**Box content:** 20 pieces

**Additional note:** The B&D Type Autoclave Test Pack is a representation of the original 7kg laundry/linen pack and tests for penetration of porous loads. (For hollow load penetration tests please use the Helix Test System.)

**Articles valid under this TDS:**

Article number	UDI-DI (GTIN)	Description	Box content
BM33001020	8720174715006	CP   B&D Type Autoclave Test Pack – 20 pcs	20 pcs

This Technical Data Sheet is issued under the sole responsibility of Blue Medical B.V.. We hereby declare that the product(s) specified above meet the indicated standards. All supporting documentation is retained at the premises of the manufacturer.

Signature:



Mr. Alex Welleweerd  
Sales Director

Place, date (dd.mm.yyyy) of issue and version:

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