

Technical Data Sheet

Manufacturers Name:	Blue Medical B.V.
Manufacturers Address:	Sluispolderweg 79, 1505HJ, Zaandam, The Netherlands
SRN (Single Registration Number):	NL-MF-000010818
Name of the Device (s):	CP Helix Test System
Product group code (s):	BM3300203*
Classification:	Non-Medical Device
Manufacturer product category:	CP
Manufacturer product group:	CP Helix Test System
Market product category:	Chemical indicators
Product color:	Ink turns from blue to pink
Product size:	Indicator strips LOT <23033-01: 75mm x 5,0mm Indicator strips LOT ≥23033-01: 75mm x 5,5mm
Applicable standards:	ISO-11140-1:2014 (Type 2) / EN 867-5:2001
Suitable processes:	STEAM
Stated Values (SV):	BM33002030: 134°C – 3,5 min. / 121°C – 15 min. BM33002031: 134°C – 3,5 min. / 121°C – 15 min. BM33002032: 134°C – 5,3 min. / 121°C – 15 min. BM33002034: 134°C – 7 min. / 121°C – 20 min.
Instructions for use:	YES, eIFU www.blue-medical.nl/eifu
HS / Customs code:	3822.9000
Shelf life:	4 years
Lead free:	YES
Latex free:	YES

DEHP / CMR free:

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:

See article summary below.

Additional note:

All Helix Test System indicators are self-adhesive. The Helix Test System tube is made of Teflon. The capsule is made of Polypropylene (PP). The connections are nylon and the O-rings are made of silicon rubber. The Helix Test System is a penetration test for hollow loads. (For porous load please use the B&D Type Autoclave Test Pack.)

Articles valid under this TDS:

Article number	UDI-DI (GTIN)	Description	Box content
BM33002030	8720174715358	CP Helix Test System 3.5 min - 100 pcs	100 pcs
BM33002031	8720174715365	CP Helix Test System 3.5 min - 400 pcs	400 pcs
BM33002032	8720174715372	CP Helix Test System 5.3 min - 100 pcs	100 pcs
BM33002034	8720174715389	CP Helix Test System 7 min - 100 pcs	100 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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