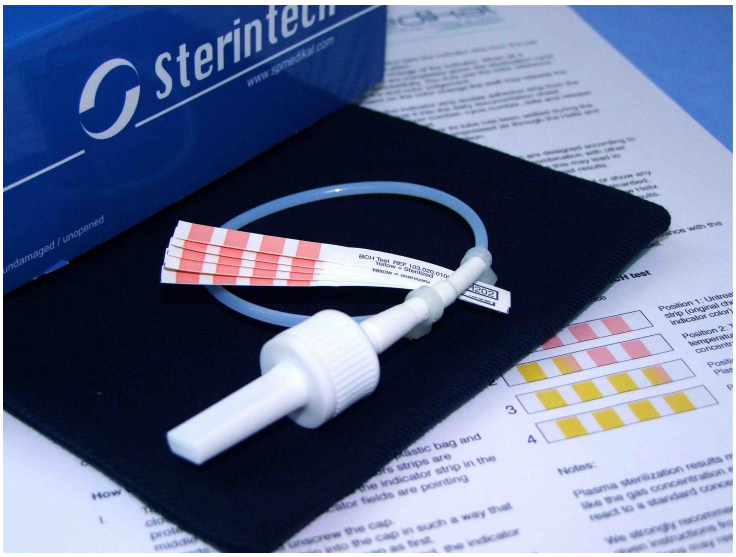
Technical Data Sheet

Product name: **Batch Control Helix Test**



Product reference:

☑ 103.020.0100 BCHT Plasma

Applicable standards:

☑ EN 867 / ISO 11140 :2014
☑ ISO 15223-1
☑ ISO 13485

Content:

Attachment(s):

☑ A Certificate of conformity
☑ B Dimensional and Material Data Helix Device

SP Medikal San. Ltd. Şti.
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BIC : TGBATRIS Branch No.: 437
IBAN: TR36 0006 2000 4370 0009 0896 01
IBAN: TR09 0006 2000 4370 0009 0896 02

1 Introduction

The Batch Control Helix Test (or BCHT in short) is a test which is recommended by the Dutch RIVM, German Robert Koch Institute and specified in the EN 285 Amendment A;2009 as a Steam sterilization performance test. Both the RIVM and Robert Koch Institue are recommending to use Helix based tests in every cycle of the steam sterilizer. SP Medikal is offering a wide range of BCHT including different chemical indicators for the different temperature / time combinations as well as for Ethylene-Oxide, Formaldehyde and Plasma

2 Description

The BCHT is based upon the EN 285 Amendment A2;2009 standard description of a Process Challenging Device and consists out of a Chemical Indicator Holder connected to a 0,25 mtr long tube. When used in every cycle the BCHT is early detecting failure during the sterilization cycles. Failures which are picked-up by the BCHT are:

✦- Sterilization temperature too low
✦- Sterilization plasma concentration too low
✦- Insufficient vacuum in depth.
✦- Insufficient air removal from hollow devices
✦- Insufficient sterilant penetration in hollow devices

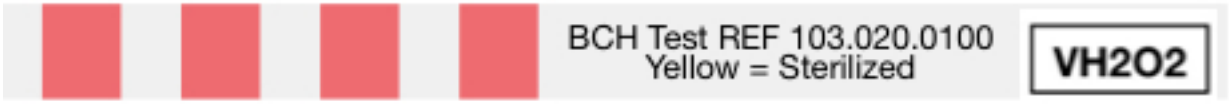
The capabilities of Helix devices of detecting failures at an early stage of their appearance is THE reason for many end-users at CSSD's to use these at a daily basis and for RIVM and Robert Koch Institute to make their recommendations.

The BCHT is consisting out of the following items:

- 1 piece of Helix device
- 100 pieces of Chemical indicator strips ISO 11140 - Type 2 with adhesive on the back
- 1 piece of Direction For Use (DFU) with color change images
- 1 piece of Carton

Each chemical indicator strip is 6 mm wide and 76 mm long. For lay-out of both front and back of the chemical indicator strip pls refer to the next page.

Lay-out:



3 Confirmation to standards

The Sterintech™ BCHT are compliant to the following standards:

Helix: EN 867 part 5 : 2001
Chemical Indicator: ISO 11140 part 1 : 2014 - Type 2

Pls refer to the attached Certificate of Conformity.

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4 Raw Materials

The Sterintech™ BCHT are consisting out of the following materials:

Helix:	See enclosed Attachment B	
Indicator strip:	HDPE	160 gsm
	Indicator Ink,	Waterbased, non solvent, non-toxic, non-heavy metals
Plastic bag:	PE - fully recyclable	
Box:	Carton, dim.: 170 x 120 x 55 mm (LxWxH)	
Box Label:	Vellum and acrylic glue, no natural latex	
Manual:	90 gr/m2 paper	

5 Quality assurance

The Sterintech™ BCHT are produced in accordance with our ISO 13485 based procedures. All working instructions and checking methods are laid-down in our Quality Assurance system which is audited twice a year internally and once year by external auditors.

All products produced by SP Medikal are traceable by lot numbers. Production files are recorded and kept for 10 years and by these every product can be traced and linked to raw materials used for the production of the product.

Re-call procedures are in forming a part of our quality manual.

6 Packaging

The Sterintech™ BCHT packed in a standard carton box as specified under 4) Raw Materials with the following dimensions: 170 x 120 x 55 mm (L x W x H)

7 Storage conditions

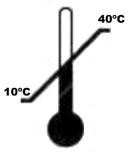
On each box the storage conditions are mentioned which guarantees the product specifications within the expiry time. Claims of non-performance of the product are subject to registered storage conditions. SP Medikal is guaranteeing the performance of the products within the specified Expiry time unless the packaging was opened or damaged.

8 Explanation of Symbols

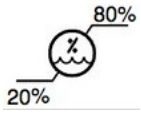
The following storage conditions symbols (ISO 15223-1) are used on the box:

Keep dry and away from fluids

Protect against UV light



Store at specified temperatures



Store at specified relative humidity

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9 Manufacturer’s declaration

Interfering substances or conditions and release of toxic substances.

On this date there are no known interfering substances or conditions that are affecting the performance of the indicators as long as they are stored as per required storage conditions.

To the best of our knowledge there are no bleeding / staining effects or releases of toxic substances in the quantities which can cause a health hazard or hazard to the goods during sterilization.

The BCHT are produced in a climate controlled production room which has been designed based upon the GMP guidelines at the following location by:

SP Medikal San Ltd. Sti.
Deliklikaya Mah. Cubuklu Cad. 39
Arnavutköy - Istanbul
Turkey

Certificate of Conformity

We, SP Medikal San Ltd Sti., represented by undersigned, herewith declare that the

Batch Control Helix Tests (BCHT) with:

- REF.: 103.020.0100 BCHT Plasma

have been tested based upon the requirements as per ISO 11140 part 1.

We herewith confirm that the BCHT's are designed and compliant to the following standard:

Helix: EN 867 - part 5, 2001 :
'Non-biological systems for use in sterilizers. Specification for indicator systems and process challenge devices for use in performance testing for small sterilizers Type B and Type S'

Chemical Indicator: ISO 11140 - part 1, 2014:
'Sterilization of health care products
Chemical indicators -- Part 1: General requirements'

Based upon these tests the chemical indicator is classified as Type 2

January 2021

Seda Küçükyilmaz
Quality Department

Peter M. den Uil (B. Sc.)
Managing Partner

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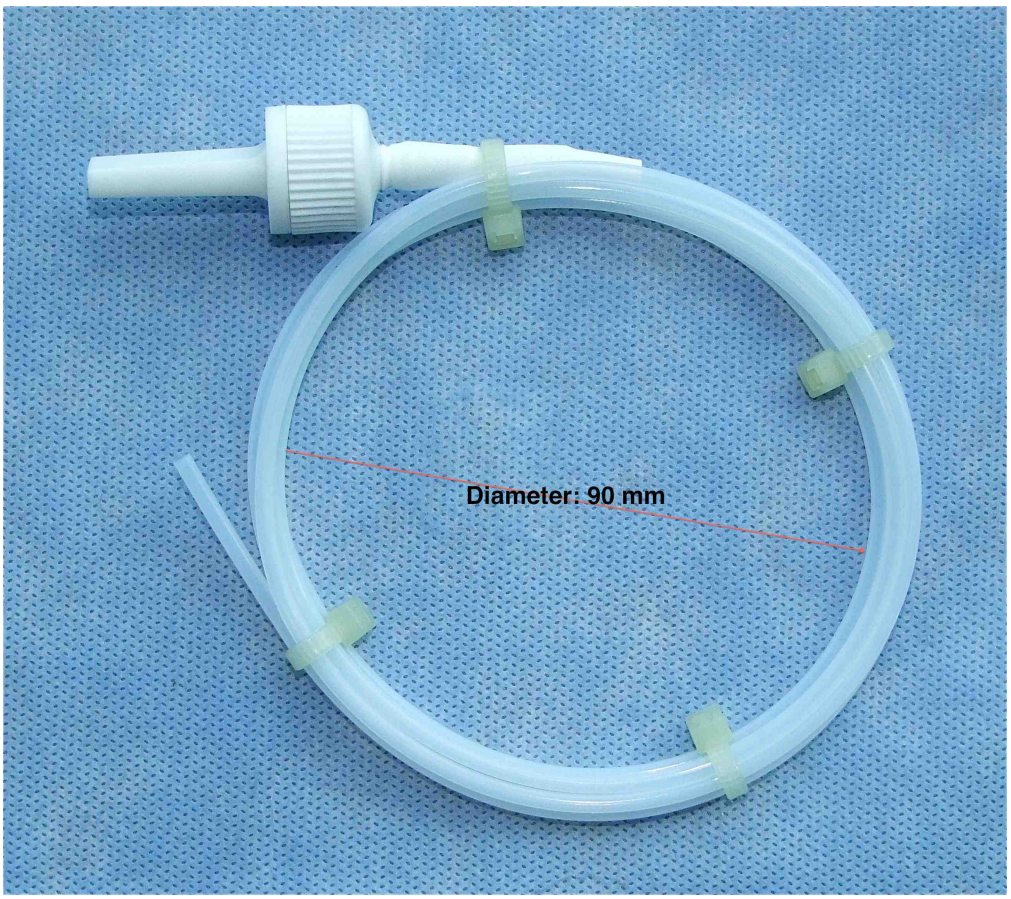
B Dimensional data Helix Device



Helix Indicator holder:	Polypropylene, white (melting point > 175°C) Dimensions: Company Confidential
Tube:	100% PTFE Virgin, Natural color, ASTM D3295 compliant Length: 0,25 mtr, ID: 2 mm, OD: 3 mm.
Sealing ring:	Silicon FDA rot (-60 - +220°C) 8 mm – internal diameter
Shrink Sleeve:	PTFE, (-55°C - + 195°C) 6 mm Internal diameter. – 40 mm length
Cable Binders:	High Temperature Resistant > 150°C for 5.000 hours Color: Natural, Material: Polyamid 4.6 Dimensions: 100 x 2,5 mm

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