

Sterimedix Ltd

Quality System Document QD 2125 Issue B
Technical Data Sheet Template

15/10/2019 -Issue 1

Technical Data Sheet- TDS14 (Scleral Markers)

Please see Appendix 1 for product specific information including ordering references & materials

1. GENERAL INFORMATION

1.1 Intended Use

Invasive device used to mark the point for any pars plana incision or injection point. They are intended for transient use.

1.2 Certification

All Sterimedix Ltd products are manufactured at the site below

STERIMEDIX FACILITY	NOTIFIED BODY
Thornhill Road North Moons Moat Redditch Worcestershire B98 9ND United Kingdom	NB Number 0123 TUV SUD Product Service GmbH, Ridlerstr. 65, D-80339 Munich

Sterimedix has appointed a European Representative (EC Rep) as per the below

Bausch & Lomb GmbH, Brunsbütteler Damm, 165-173, 13581, Berlin, Germany

1.3 Packaging Materials

Primary packaging

Either -

Blister - Pentamed® Film (PET'G'/'A'PET/PET'G')

Blister lid - Tyvek® with all over lacquer

or -

In Protector without blister – Protector – Polyethylene

Secondary packaging –

Sterile: Box - White Board

Sterile or Non-Sterile: Bulk - Double PE sealed bags labelled on the inner bag

1.4 Materials of Concern

MATERIAL	DECLARATION
DEHP/Phthalates	Devices do not contain referenced material
Latex	Devices do not contain referenced material
PVC	Devices do not contain referenced material
Bisphenol A (BPA)	Some devices may contain very low levels of BPA CAS 80-05-7 as a residue from the epoxy synthesis process which is used as a bonding agent. However, levels are below the 0.1% SVHC threshold

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Substances of animal origin	Devices do not contain referenced material
Conflict Minerals	Devices are free from any Conflict Minerals referring to gold, tin, tantalum and tungsten, the derivatives of cassiterite, columbite-tantalite and wolframite, extracted in the Democratic Republic of the Congo (DRC) and surrounding countries.

1.5 REACH

Based on current available information Sterimedix has not been able to identify any substances above 0.1% in any of its final devices which have been included on the Candidate List as a SVHC.

1.6 Instructions for Use (IFU)

As per Annex I, 13.1, Paragraph 4 by way of exception, no such instructions for use are needed for devices in Class I or IIa if they can be used safely without any such instructions. Therefore, unless otherwise stated, Sterimedix does not provide IFU's.

1.7 Shelf Life

Shelf life for all Sterile devices is 5 years

Non-Sterile N/A

There are no specific storage or transport conditions. Generic instructions such as Store in a cool dry place, keep out of direct sunlight, do not use if box is damaged are displayed on the box packaging with the appropriate symbology.

1.8 Sterilisation, Resterilisation/Reprocessing

All Sterimedix devices are validated to be sterilised via EtO Cycle 25 only at the Sterigenics Plant in Derbyshire*. After initial sterilisation, Sterimedix devices may be resterilised using the same EtO cycle once more. Sterimedix devices can be sterilised a maximum of two times**.

*Those using another EtO sterilisation cycle for Sterimedix devices are responsible for validating their own cycle to ensure sterility has been achieved and can be maintained.

**Some devices may have already undergone two sterilisation cycles before leaving Sterimedix. This will be represented by a "Z" at the end of the Lot number of the batch.

Further information be found in declaration "ST41 Sterimedix Sterilisation reprocessing instructions".

1.9 Sterile & Non-Sterile products

Non-Sterile devices are identical to Sterile devices in materials, manufacturing and control, with the exception of the packaging- and sterilisation-process

1.10 Classification

Class IS/IM in accordance with Annex IX Rule 5

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1.11 GMDN Code

GMDN code is 12442

2. LABELLING

2.1 Example Label(s)



LBL00009 – Sterile boxes of 10



LBL00020 – Sterile bulk




LBL00012 – Non-Sterile blister bulk

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REF 7500NS-02 **Qty:100** 

3.5mm/4.0mm
Ophthalmic Caliper (Scleral Marker)

 **LOT** 000000 **CE**
0123

Sterimedix Ltd 1 Madeley Road, North Moors Moat, Redditch,
B98 9NB, UK

Fragile Tips - Suitable for sterilisation by ETO using a validated cycle
Must be sterilised before use

LBL0026 – Non-Sterile boxes of 100

REF M7500 **Qty:50**

3.5mm/4.0mm
Ophthalmic Caliper
(Scleral Marker)



21IND01: 85056030402298
EXPI17: 000000
LOT108: 000000

LOT 000000  0000-00-00

LBL0030 – Sterile boxes of 50

3. DISCLAIMER

All information has been collated to the best of our knowledge and based on information currently available to us. This document can be updated without further notification.

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Appendix 1- Product specific information

PRODUCT SUB-GROUP	PRODUCT CODE	LABEL DESCRIPTION	HUB COLOUR	ORDERING REFERENCE	MATERIALS
Scleral Markers	M7500	3.5mm/4.0mm Ophthalmic Caliper (Scleral Marker)	N/A	M7500-02/10, M7500-02/50, 7500-02/Y	ABS
	7500NS	3.5mm/4.0mm Ophthalmic Caliper (Scleral Marker)	N/A	7500NS-02/100/Y, 7500NS-02/Y	
Scleral Incision Templates	M7510	3.5mm Scleral Fixation Incision Template	N/A	M7510, M7510-02/10, M7510-02/50	Polycarbonate
	7510NS	3.5mm Scleral Fixation Incision Template	N/A	7510NS-02/100/Y	

KEY	
REFERENCE	DEFINITION
-02/X	Sterile, Blister Packed, Box of X
NS-02/Y	Non-Sterile, Blister Packed, in Bulk
-02/Y	Sterile, in Bulk
NS-02/100/Y	Non-Sterile, Box of 100