Product Service

Choose certainty.
Add value.

ST Assessment Report Plasma
Report No. 0713134086 /ST

Project Handler:	Rolf Schmiegel
Legal Manufacturer:	Shinva Medical Instrument Co. Ltd. Xinhua Medical Scientific Zone, Zibo New & Hi-Tech Industrial Zone Shandong Province 255086 P.R. China
Sterilization Facility:	Shandong Xinhua Medical Co. Ltd. No. 2009 Xinhua Avenue Zhoucun District, Zibo City Shandong Province [23, p 15]
Purpose of examination:	Evaluation whether the criteria concerning the correct cycle development of Plasma sterilization is in compliance with the applicable requirements 93/42/EEC and relevant standards and guidelines.
Documentation	Cycle Development of Plasma sterilization for Plasma Sterilizers (see chapter 1.2 for applicable Sterilizers), Design Dossier for **MDD-NEW-1**
Assessment criteria:	- EN 556-1:2001 + AC:2006 - EN ISO 14937:2010
Result:	*The above-mentioned process for Plasma sterilization is in compliance with* 93/42/EEC *and the applicable requirements of the relevant standards and guidelines.* ***SEE REMARK SECTION FOR LIMITATIONS.***

Digitally signed by Latîşev Anastasia
Date: 2024.03.16 19:02:31 EET
Reason: MoldSign Signature
Location: Moldova

Phone: (+ 49) 089 500 84299
E-Mail: rolf.schmiegel@tuev-sued.de

TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 Munich
Germany

Product Service

Choose certainty.
Add value.

Documentation history	Handed in on: See 1.3.

Phone: (+ 49) 089 500 84299
E-Mail: rolf.schmiegel@tuev-sued.de

TÜV®

TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 Munich
Germany

2.7 Routine Process

Shandong Xinhua gives recommendation regarding to physical, chemical and biological monitoring [36, p 101 + 102].

Data printing: As soon as the sterilization is finished, the buzzer sounds for 4 seconds and the printer starts to print the data [36, p 59].

2.8 Requalification Requirements

New sterilizer installation, displacement, repair, sterilization failure, change of packaging material or sterilizing items should be reevaluated, including physical monitoring, chemical monitoring and biological monitoring (three consecutive tests). After the all of the monitoring is qualified, the sterilizer can be used.

[8, p 109] Recommendation of Shandong Xinhua Medical Instrument Co. Ltd

3. Remarks

a) Product functionality testing of the final sterilized medical device is not the topic of Shandong Xinhua Medical Instrument Co. Ltd. (recommendation of material suitability was given). Due to the fact that the sterilization process is possible to affect in a negative way the Medical Device, Shandong Xinhua Medical Instrument has to update the technical documents according to the requirements of EN ISO 14937: 2010, 5.4.2, i.e. the effect of the sterilization process related to the final medical device itself is in the responsibility of the medical device manufacturer and has to evaluate by himself.

   The updated documentation has to be submitted within 3 months after Approval to TÜV SÜD.

b) A special audit by a STA for non standard sterilization methods of the production facility where production of the Biological Indicators takes place to confirm that the production processes meet the requirements of production to EN ISO 11138-X. This special audit to also include a full review of the resistometer that was used for this study that is under review. This special audit can be conducted up to 6 month's time and does not hold up the approval of this project.

4. Conclusions

The reviewed validation documentation for the validation of Plasma Sterilization **is in compliance** with Directive 93/42/EEC and the applicable requirements of the relevant standards and guidelines.

Phone: (+49) 089 500 84299
E-Mail: rolf.schmiegel@tuev-sued.de

TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 Munich
Germany

However, the item 3a in section 3 need to be addressed latest within 3 months after Approval and item 3b within 6 months after approval.

The conclusion in this report is based on the information submitted by the manufacturer.

TÜV SÜD Product Service

i.A. Jeff Vest
Non-Active Medical Devices + Monitoring
Reviewer

TÜV SÜD Product Service GmbH

i.A. Rolf Schmiegel
Non-Active Medical Devices

We hereby declare that we act independent and impartial when assessing the device or processes, as required in Regulation (EU) 745/2017, Regulation (EU) 746/2017 and Implementing Regulation (EU) 920/2013.

Phone: (+ 49) 089 500 84299
E-Mail: rolf.schmiegel@tuev-sued.de

TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 Munich
Germany