bluepoint medical GmbH & Co. KG
An der Trave 15
23923 Selmsdorf, Germany
www.bluepoint-medical.com
Phone: +49 (0) 38823 54880
Fax: +49 (0) 38823 548829

DECLARATION LETTER

We, bluepoint medical GmbH & Co. KG, located at, An der Trave 15, 23923 Selmsdorf, Germany, hereby declare the compliance of the marketed medical reusable temperature sensors with the essential requirements of the product reprocessing standards listed below.

a) Manual reprocessing, validation according to ISO 15883-5, AAMI TIR 30:2011/R2016 and AAMI TIR 12:2010, test report no. SN30535b

b) Automatic reprocessing, validation according to ISO 15883-5, AAMI TIR 30:2011/R2016 and AAMI TIR 12:2010, test report no. SN30535a

c) Hot steam sterilisation, validation according to ISO 11737-2:2009, Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labelling – Guidance for Industry and Food and Drug Administration Staff (FDA), AAMI TIR 30:2011, AAMI TIR 12:2010 und Comprehensive Guide to steam sterilization and sterility assurance in health care facilities (ANSI/AAMI ST79:2010 and A1:2010 and A2:2011 and A3:2012 and A4:2013), test report no. SN30535c

The validated reprocessing procedures for manual and automatic reprocessing as well as for hot steam sterilisation on which the product tests were based were carried out on the skin sensors, as these represent the most complex product in the portfolio in terms of design (material mix, gaps, different surfaces, etc.); the residual protein (as required in HTM 01-01) and the TOC value (total organic carbon) after reprocessing were evaluated.

In the case of hot steam sterilisation, the test was carried out in the pre-vacuum process at 132°C in a half cycle (1.5 min holding time) and at gravity at 132°C in a half cycle (5 min holding time); process control via bio-indicator; acceptance criterion: germ reduction by 6 log levels. With regard to product durability, the tests were carried out at 134°C / 5 min, as the higher thermal load is to be expected here.

The information on reprocessing the temperature sensors (according to ISO 17664) is given in the instructions for use, current edition. The instructions for use also contain information on non-approved procedures.

With reference to the requirements for electrical safety and performance data (product standard ISO 80601-2-56), the test was carried out before and after performing 100 reprocessing cycles in accordance with the manufacturer's specifications. The results are documented in the test report no. 419186_3 SEB 80601-2-56 Sensatronic TS.

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Name: Ralf Dettweiler

Function: Project Manager
Temperature Sensors