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Bluepoint medical GmbH & Co. KG

An der Trave 15
23923 Selmsdorf
Germany

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Expiry Date : 03 November 2017

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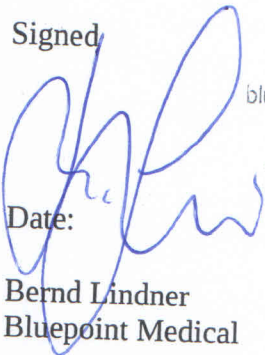
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The following documentation can be made available direct to notified bodies upon request.

Signed



bluepoint medical GmbH & Co. KG
An der Trave 15
D-23923 Selmsdorf
Tel.: +49(0) 38823-548-8001
Fax: +49(0) 38823-548-8029

Date:

Bernd Lindner
Bluepoint Medical

Date November 3, 2016

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Technical File 47 Capnographs

Person(s) responsible for this documentation: Heidi Froehlich
Contact Email: h.froehlich@bluepoint-medical.com

- Solutions adopted to fulfill the essential requirements.
- Design input specification.
- Manufacturing process flow chart.
- Risk management document for the system.
- Detailed test results device verification.
- Software verification and validation reports and risk assessment EN 62304.
- Evidence of usability human factors assessment.
- Details of clinical investigations.
- Medicinal substance human blood derivatives animal tissues.
- Classification rationale.

Technical File 45 Flow Sensors

Person(s) responsible for this documentation: Nedyalko Radev
Contact Email: n.radev@bluepoint-medical.com

- Solutions adopted to fulfill the essential requirements.
- Design input specification.
- Manufacturing process flow chart.
- Risk management document for the system.
- Detailed test results device verification.
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- Evidence of usability human factors assessment.
- Details of clinical investigations.
- Medicinal substance human blood derivatives animal tissues.
- Classification rationale.

Date November 3, 2016

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Technical File 33 / 40 Finger Pulse Oximeters

Person(s) responsible for this documentation: Heidi Froehlich
Contact Email: h.froehlich@bluepoint-medical.com

- Solutions adopted to fulfill the essential requirements.
- Design input specification.
- Manufacturing process flow chart.
- Risk management document for the system.
- Detailed test results device verification.
- Software verification and validation reports and risk assessment EN 62304.
- Evidence of usability human factors assessment.
- Details of clinical investigations.
- Medicinal substance human blood derivatives animal tissues.
- Classification rationale.

Technical File 23 Pulse Oximeters

Person(s) responsible for this documentation: Heidi Froehlich
Contact Email: h.froehlich@bluepoint-medical.com

- Solutions adopted to fulfill the essential requirements.
- Design input specification.
- Manufacturing process flow chart.
- Risk management document for the system.
- Detailed test results device verification.
- Software verification and validation reports and risk assessment EN 62304.
- Evidence of usability human factors assessment.
- Details of clinical investigations.
- Medicinal substance human blood derivatives animal tissues.
- Classification rationale.

Date November 3, 2016

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Technical File 97 VersaStream Capnography Sampling Lines

Person(s) responsible for this documentation: Rayk Juergensen
Contact Email: r.juergensen@bluepoint-medical.com

- Solutions adopted to fulfill the essential requirements.
- Design input specification.
- Manufacturing process flow chart.
- Risk management document for the system.
- Detailed test results device verification.
- Software verification and validation reports and risk assessment EN 62304.
- Evidence of usability human factors assessment.
- Details of clinical investigations.
- Medicinal substance human blood derivatives animal tissues.
- Classification rationale.
-

Technical File 31 Pulse Oximetry Sensors - 4000 Series

Person(s) responsible for this documentation: Ralf Dettweiler
Contact Email: r.dettweiler@bluepoint-medical.com

- Solutions adopted to fulfill the Essential Requirements
- Design input specification
- Manufacturing process flow chart
- Risk management document for the system
- Detailed test results Device verification
- Software verification and validation reports and risk assessment EN 62304
- Evidence of Usability Human factors assessment
- Details of Clinical investigations
- Medicinal substance human blood derivatives animal tissues
- Classification rationale

Date November 3, 2016

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Technical File 27 Temperature Probes

Original Manufacturer Sensatronic GmbH Alter Holzhafen 19 – 23966 Wismar Germany
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Pilatuspool 2 – 20355 Hamburg – Germany

MEDCERT Identification No. 0482

Person(s) responsible for this documentation: Nedyalko Radev, Jens Schwarz
Primary Contact Email: n.radev@bluepoint-medical.com
Contact Email: j.schwarz@sensatronic.com

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- Manufacturing process flow chart.
- Risk management document for the system.
- Detailed test results device verification.
- Software verification and validation reports and risk assessment EN 62304.
- Evidence of usability human factors assessment.
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