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

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Date November 3, 2016

Technical File 47 Capnographs

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- 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

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- 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 33 / 40 Finger Pulse Oximeters

Person(s) responsible for this documentation: Heidi Froehlich
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- 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

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- 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

Technical File 97 VersaStream Capnography Sampling Lines

Person(s) responsible for this documentation: Rayk Juergensen
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- 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
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- 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

Technical File 27 Temperature Probes

Original Manufacturer Sensatronic GmbH Alter Holzhafen 19 – 23966 Wismar Germany
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- 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