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| Sensatronic GmbH Wismar | Declaration of Incorporation | Dok.-Nr.: 715005.1 Declaration of Incorporation OEM-Flow A.doc |
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Declaration of Incorporation of partly completed medical products

We,

Manufacturer: Sensatronic GmbH
Am Ring 9
23970 Wismar, Germany

EU Representative: n. a.

declare, that the following partly completed medical product

Model, Type: OEM-Flow A Module, OEM-Flow A-F Module

Description: Module for gas flow measurement with hot wire flow sensors

Function: Operates with hot wire sensors and generates continuous flow data stream via a serial interface

complies with the essential requirements of the Medical Device Directive 93/42/EEC. For this partly completed medical product a Technical Documentation according Annex I has been established. The applicable parts of the following regulations and standards have been considered for the compilation of this Technical Documentation:

ISO 80601-2-12:2011 (Accuracy of flow measurement for critical care ventilators)

We obligate to transmit the Technical Documentation according Annex I for this partly completed medical to the national authorities in response to a reasoned request.

This partly completed medical product may be put into service only if the requirements for safe incorporation and application are completely established and for the final medical product into which it is to be incorporated has been declared the conformity with the essential performance according Annex I of 93/42/EEC.

Place, Date: Wismar, 2017-02-20

Responsible person: J. Schwarz

Signature:



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| erstellt: 2017-02-20 | geprüft: B. Schmidt QM-Berater | freigegeben: J. Schwarz Geschäftsleitung |
| Vorlage: 715005 Declaration of Incorporation.doc | Erstellt: 2015-04-13 | Sensatronic GmbH |