

## Declaration of Conformity

We, MS Westfalia GmbH, having the legal address and the place of production in Junkersring, 54, 53844 Troisdorf, Germany,

declare under our sole responsibility, that the product fulfills all applicable requirements of the directive 93/42/EEC considering the amendments by the directive 2007/47/EC.

|                    |                                                                                |
|--------------------|--------------------------------------------------------------------------------|
| Name               | <b>Jenny Defibrillation Module (Jenny DM)</b><br>Device for intensive care use |
| Risk class<br>GMDN | IIb according rule 9<br>Defibrillator (48048,17882)                            |
| from serial        | 1515101521201701 to 1515XXXXXXXXXXXXXX                                         |
| REF Number         | 0104.00.00000.000                                                              |

|                    |                                                                             |
|--------------------|-----------------------------------------------------------------------------|
| Name               | <b>Jenny Ventilation Module (Jenny VM)</b><br>Device for intensive care use |
| Risk class<br>GMDN | IIb according rule 9<br>Ventilator (42411)                                  |
| from serial        | 1415101521201701 to 1415 XXXXXXXXXXXXXXXX                                   |
| REF Number         | 0102.00.00000.000                                                           |

|                    |                                                                                         |
|--------------------|-----------------------------------------------------------------------------------------|
| Name               | <b>Jenny Monitoring Module (Jenny MM)</b><br>Device for intensive care use              |
| Risk class<br>GMDN | IIb according rule 10<br>Physiological Monitoring System (33586,35569,<br>36552, 62911) |
| from serial        | 1615101521201701 to 1615 XXXXXXXXXXXXXXXX                                               |
| REF Number         | 0103.00.00000.000                                                                       |

Standards used: EN 60601-1:2012  
EN 60601-1-2:2014  
EN 60601-1-12:2014 (10.1.4/D0160G)  
EN 794-3:2009  
ISO 10651-3: 1997  
EN 1789:2014

The assessment of the conformity of the product was performed in compliance with annex II section 3 of the directive 93/42/EEC by the

Notified body:

BSI Group The Netherlands B.V.  
Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands

Identification number CE 2797

Valid till: 15.11.2023

Place and Date: 11.06.2019



Eugen Kagan, General Manager