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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 576973**

Issued To: **MS Westfalia GmbH**
Junkersring 54
53844 Troisdorf
Germany

In respect of:

The design, development and manufacture of ventilators, vital parameter monitoring and defibrillator systems for intensive care, anaesthetic machines and X-ray imaging systems.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Albert Roossien, Regulatory Lead

First Issued: **2016-06-20** Date: **2019-03-20** Expiry Date: **2023-11-18**

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Supplementary Information to CE 576973

Issued To:

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Number	Device Name	Intended purpose per IFU
Class IIb		
42411	Bellavista	Ventilator
42411	Inspirer	Ventilator
42411	MythoVent	Ventilator systems + Vital Parameter Monitoring for intensive care
42411, 62911, 48048, 36552, 35569, 33586, 17882	Jenny	Ventilator+Vital Parameter Monitoring+Defibrillators for intensive care with docking station
47769	Maja Maja X	Anaesthesia machine
37630, 37672	Gaia	Mammography unit
37626, 37612	ARES	Mobile X-Ray
37644, 37645	ARES	Stationary X-ray system

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