

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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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

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Supplementary Information to CE 576973

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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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