

BUREAU VERITAS
Certification



Shvabe-Zurich GmbH

Talacker 42, CH-8001 Zurich - SWITZERLAND

Certified site:

Schaffhauserstrasse 560, 8052 Zürich - SWITZERLAND

Bureau Veritas Italia S.p.A. certifies that the Full Quality Assurance System of the above organization has been audited and found to be in accordance with the requirements of

DIRECTIVE 93/42/EEC

(in accordance with Annex II - excluding paragraph 4)

In relation to the following products

Product subcategory :	See Annex
Generic group:	See Annex
Model:	See Annex
Class:	See Annex

(may refer to the Annex of the certificate that lists all the products / models of devices subject to certification)

Reference BV practice: ZIG. N. **9401011**

Original cycle start date: **20 September 2018**

Expiry date of previous cycle: **N/A**

Certification / Recertification Audit date: **6 December 2017**

Certification / Recertification cycle start date: **20 September 2018**

Subject to the continued satisfactory operation of the organization's Management System, this certificate expires on: **19 September 2023**

Certificate No. - Version: **IT285277 - 2**

Revision date: **13 May 2021**

GIORGIO LANZAFAME - Local Technical Manager

This certificate is issued by Bureau Veritas Italia S.p.A. Viale Monza, 347-20126 Milan, as a notified body for the Directive 93/42/EEC, with identification number 1370

Further clarifications regarding the scope of this certificate and the applicability of the management system requirements may be obtained by consulting the organisation. To check this certificate validity please refer to the website www.bureauveritas.it





Annex to the CE Certificate n° IT285277 - 2

Subcategory:	Respiratory devices, devices for oxygen therapy, anesthesia for inhalation	
Generic group:	Model:	Class:
Infant nasal respiratory breath support device	APDN-01 - «UOMZ»	Ila
Breathing mixtures humidifier	TEVLAR - «UOMZ»	Ila
Multifunctional inhalation anesthesia device for adults and children	MAIA-01	Ilb
Subcategory:	Devices for stimulation or inhibition	
Generic group:	Model:	Class:
Neonatal irradiator for phototherapy	OFN-02 - «UOMZ», OFN-03	Ila
Subcategory:	Devices for hypothermia / hyperthermia	
Generic group:	Model:	Class:
Neonatal table with automatic heating temperature control	SNO – UOMZ	Ila
Neonatal infrared heater	«Radiant heat-BONO»	Ila
Infant neonatal heater	ODN-01-«UOMZ»	Ila
Intensive care infant incubator	IDN-02-UOMZ, IDN-03 - «UOMZ»	Ilb

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