

Free Sales Certificate

Certificate n° 00000507

Valid until 15.01.2022

The SWISS AGENCY FOR THERAPEUTIC PRODUCTS, SWISSMEDIC, authorizes and supervises therapeutic products (medicinal products and medical devices). In Switzerland medical devices are regulated under the Federal Act on Medicinal Products and Medical Devices (Therapeutic Products Act, TPA; SR 812.21) and the Medical Devices Ordinance (MedDO; SR 812.213) which incorporates the European legislation. On the basis of the documents submitted, Swissmedic certifies that the device(s) of the medical device category **Infant Photo-and Thermotherapy Devices** specified hereunder can be placed on the market in Switzerland and its treaty countries without restrictions.

- see attached list of 1 page(s)

Companies involved in the manufacturing or the supplying of these medical devices:

- **Ordering company:** Shvabe-Zurich GmbH, Talacker 42, 8001 Zurich, CH (Role: Legal manufacturer)

Bern, 15.01.2019

Swiss Agency for Therapeutic Products

Medical Devices Division

Andrea Spring



List of Medical Devices

Medical Devices	Model	Class	Intended use	Form
Category: Respiratory devices, devices for oxygen therapy, anesthesia for inhalation				
Infant nasal respiratory breath support device	APDN-01-«UOMZ»	Ila	Destined for use while performing respiration therapy of newborn without intubation	Not sterile
Breathing mixtures humidifier	TEVLAR - «UOMZ»	Ila	Intended for heating and increase of the water content of breathing mixture coming to the patient from the artificial lung ventilation device (ventilator), the inhalational anesthesia device or the oxygen inhaler	Not sterile
Multifunctional inhalation anesthesia device for adults and children	MAIA-01	IIb	Intended for carrying out of inhalation anesthesia (IA) in any breath circuit with chirurgical interventions of any complexity providing artificial ventilation of lungs) and monitoring of parameters of IA, artificial pulmonary ventilation and also of vitally important functions of the patient's organism.	Not sterile
Category: Devices for stimulation or inhibition				
Neonatal irradiator for phototherapy	OFN-03	Ila	Used for treatment of hyperbilirubinemia for infants by means of reducing the concentration of indirect bilirubin in blood by irradiation of infant's skin with light flux of 430-530 Nm spectral range.	Not sterile
Neonatal irradiator for phototherapy	OFN-02-«UOMZ»	Ila	Intended for treatment of inogenous jaundice	Not sterile
Category: Devices for hypothermia / hyperthermia				
Intensive care infant incubator	IDN-03-«UOMZ»	IIb	Intended for nursing and intensive therapy of premature and weak infants (from 500 gr)	Not sterile
Intensive care infant incubator	IDN-02-UOMZ	IIb	Intended for nursing and carrying out of effective resuscitation of premature and weakened babies	Not sterile
Neonatal table with automatic heating temperature control	SNO-UOMZ	Ila	Designed for adaptation of the newborns and care for the newborns and for recovery of their vital functions	Not sterile
Infant neonatal heater	ODN-01-«UOMZ»	Ila	Intended for heating of newborns, inclined to hypothermia	Not sterile
Neonatal infrared heater	«Radiant heat-BONO»	Ila	Intended to be used as a basic or additional heat source and also for treatment of hyperbilirubinemia during nurse and therapy of neonates	Not sterile

