



# Company's Profile



**John McGough**  
Managing Director  
(Switzerland)

**Date of foundation:** 8/3/2007

**Legal address:** Talacker 42, CH 8001, Zurich

Shvabe-Zurich GmbH (Switzerland) is a labeled manufacturer that is responsible for design of the goods, control of quality standards, maintenance and sales to medical centers and hospitals worldwide

***High technologies from the first day of life, culture, based on traditions, innovative development and openness to everything new.***

***We save the future!***

# Goals & Objectives



- High Quality Service and maintenance of Shvabe products within Europe and the Far Abroad
- Promotion and increase of sales of high-tech products worldwide
- Encourage investments and new technologies to develop innovative products
- Establish industrial and business long-lasting cooperation with partners
- Search for new market opportunities in the delivery of components and utilities for our products

# Quality Management

High quality of equipment is approved by international Quality management systems in accordance with the requirements of DIRECTIVE 92/43/EEC and Free Sales Certificate



**CE Certificate**  
Issued to:

**Shvabe-Zurich GmbH,**  
Registered office:  
Talacker 42, CH-8001 Zurich, Switzerland  
Operative site:  
Schaffhauserstrasse 550, 8052 Zurich, 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 as amended**  
(in accordance with Annex II - excluding paragraph 4)

In relation to the following products:

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 cert. n. 2182 N. 50540135

Certification cycle start date: **20 September 2018**  
Subject to the continued satisfactory operation of the organization's Management System, this cert. expires on: **19 September 2021**  
Original certification date: **20 September 2018**

Certificate N. **IT285277** Rev. N. 1 of: **20 September 2018**

*Andrea Pulpan*  
Andrea Pulpan - Local Technical Manager

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**Annex CE Certificate**  
**IT285277**

Subcategory:	Respiratory devices, devices for oxygen therapy, anaesthetic for... in a clinic	
Generic group:	Model:	Class:
Infant nasal respiratory breath support device	APDN-01 - «UOMZ»	Ila
Urostomy mixture by... rifier	TLVLAK - «UOMZ»	Ila
Multi-function... inhalation anaesthesia device for adults & in children	MAA-01	Ilb
Subcategory:	Devices for stimulation or... inhibitor	
Generic group:	Model:	Class:
Neonatal irradiat... for phototherapy	OFN-02 - «UOMZ», OFN 03	Ia
Subcategory:	Devices for... in... therapy	
Generic group:	Model:	Class:
Neonatal table with automatic heating temperature control	SNO - UOMZ	Ila
Neonatal infrared heater	«Nacim» heat-BONO»	Ila
Infrared neonatal heater	ODN-01 «UOMZ»	Ila
Infant neonatal heater	IDN 02 UOMZ, IDN-03 - «UOMZ»	Ilb

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**FREE SALES CERTIFICATE**

Nr.: FSC-16-21336 valid until: 14 June 2019

The SWISS AGENCY FOR THERAPEUTIC PRODUCTS certifies herewith, that medical devices are regulated in Switzerland under the Federal Law on Medicinal Products and Medical Devices (Law on Therapeutic Products) of 15 December 2000 in force since 1 January 2002 and the Medical Devices Ordinance of 17 October 2001 in force since 1 January 2002.

The following medical device(s) meets (meet) the legal requirements set out in the Swiss Medical Devices Ordinance and which incorporates the Medical Devices Directives of the European Union:

- Infant Photo- and Thermo-therapy Devices
- Intensive Care Infant Incubator IDN-03 UOMZ
- Intensive Care Infant Incubator IDN-02 UOMZ
- Neonatal Phototherapy Irradiator OFN-02 UOMZ
- Neonatal Table with Automatic Heating Temperature Control SNO-UOMZ
- Infant Neonatal Heater ODN-01 UOMZ

Therefore, the firm Shvabe-Zurich GmbH, Talackerstr. 42, CH-8001 Zurich, Switzerland,

in conformity with the medical devices law of Switzerland is authorized to develop, manufacture and sell on the Swiss market and to export into any country the CE marked medical device(s) above-mentioned.

This certificate is valid until 14 June 2019

Bern, 15 June 2016

Swiss Agency for Therapeutic Products  
Medical Devices Ordinance

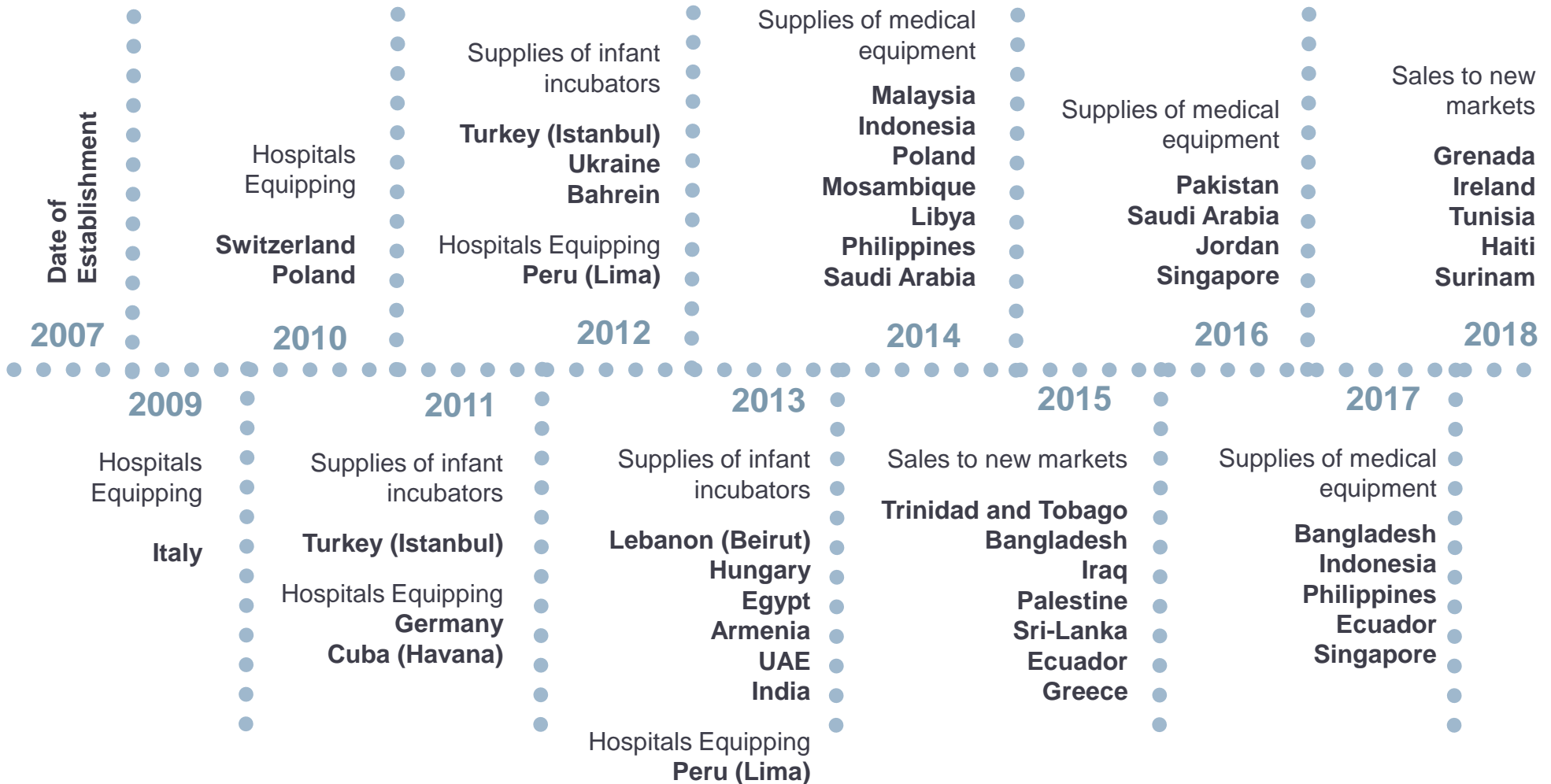
*Claude-Philippe Peitpierre*  
Claude-Philippe Peitpierre, Master of Law

Fee: CHF 300.00

Schweizerische Eidgenossenschaft  
Confédération suisse  
Confederazione Svizzera  
Confederaziun svizra  
Swiss Agency for Therapeutic Products

Swissmedic | Hohenstrasse 7 | Postfach | CH-3000 Bern 9 | www.swissmedic.ch | Tel. +41 58 462 02 11 | Fax +41 58 462 02 12

# Achievements & Projects



# Medical products

- Incubators



Incubator IDN-03

- Heaters



Incubator IDN-02

- Anesthesia



Multifunctional device of inhalation anesthesia MAIA-01

- Phototherapy



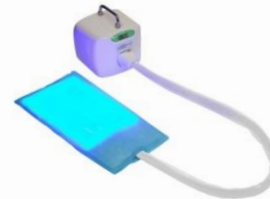
Neonatal table SNO



Phototherapy irradiator OFN-02



Phototherapy irradiator OFN-03



Fiberoptical system for neonates phototherapy "Biliflex",  
launched in 2017



Heater for neonates ODN-01



Neonatal heater "Radiant heat"-BONO,  
launched in 2017

# Innovative medical products



Incubator-transformer  
BONO



Open resuscitation system  
ORS-BONO



Neonatal table  
SNO-BONO



Portable neonatal incubator  
BONNY



Artificial lung ventilation device  
AIVL-01

# Marketing & Promotion

- Annual participation at international congress of neonatology **GNPI** (Germany, Switzerland) and international medical exhibitions **Medica** (Dusseldorf) and **Arab-Health** (Dubai)
- Participation in the projects of complex turnkey equipping of state medical centers and hospitals
- Regular training programs for customers and technical specialists of our distributors
- Direct deliveries of medical equipment to hospitals of Europe, Asia, Africa and Latin America





Thank you for your attention!

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