Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

# EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

## No. G1 075182 0006 Rev. 00

**Manufacturer:**
**PULSION Medical Systems SE**
Hans-Riedl-Straße 17
85622 Feldkirchen
GERMANY

**Facility(ies):**
PULSION Medical Systems SE
Hans-Riedl-Straße 17, 85622 Feldkirchen, GERMANY

**Product Category(ies):**
**Patient monitors including compatible modules, accessories and disposables for hemodynamic monitoring and measurement of blood pressure, cardiopulmonary, circulatory and organ function variables**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

**Report No.:** 713153619

Digitally signed by Dubalari Pavel
Date: 2023.02.20 12:30:34 EET
Reason: MoldSign Signature
Location: Moldova

**Valid from:** 2019-05-17
**Valid until:** 2023-05-24

**Date,** 2019-05-17

Stefan Preiß


TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

# Declaration of Conformity

**Declares under our sole responsibility that the product to which this declaration relates is in conformity with the provisions of Council Directive 93/42/EEC (Medical Device Directive, MDD).**

**Manufacturer & address**

PULSION Medical Systems SE
Hans-Riedl-Str. 17
85622 Feldkirchen
Germany

| | |
|---|---|
| **Product Name** | PiCCO Module |
| **Product Model Number** | PC4510 |
| **Device Classification** | IIb according Annex IX, Rule 10 |
| **GMDN Code** | 36561, Patient monitoring system module, cardiac output |

**PULSION Medical Systems SE is assessed to**
**EN ISO 13485:2016 and Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)** by the following Notified Body:

**TÜV SÜD Product Service GmbH**
**Ridlerstraße 65**
**80339 Munich**
**Germany**

**Identification Number 0123**

**This declaration of conformity is valid in combination with the following certificates or until the next substantial change of the product:**

- **the EC Certificate No. G1 075182 0006**
  **(expiration date** 26 May. 2024**)**

PULSION Medical Systems SE
Feldkirchen, 17 Jun. 2020

**Jens Anter**
Head of Quality Management &
Regulatory Affairs

**Stephan Haft**
Managing Director

Getinge Slovakia, s. r. o., Pribinova 25, 811 09 Bratislava

# Authorization Letter

Date: 25.3.2021

We, company GETINGE Slovakia, s. r. o., Pribinova 25, 811 09 Bratislava

Herewith confirm that: **Endo Chirurgie SRL**

**Is our authorized and official Distributor for the whole territory of** Moldova **for the following companies part of Getinge Group:**

**PULSION Medical Systems SE, Hans-Riedl-Str. 17, 85622 Feldkirchen, Germany**

Therefore, who are official manufacturers of **Patient monitors including compatible modules, accesories and disposables for hemodynamic monitoring and measurement of blood pressure, cardiopulmonary, circulatory and organ function variables**, having factories at **Hans-Riedl-Str. 17, 85622 Feldkirchen, Germany**, assign **Endo Chirurgie SRL**, based in **Str. Mesterul Manole 9**, **MD 2023**, **Chisinau**, **Republic of Moldova**, as authorized representative in correspondence with the conditions if directive 93/42/EEC, 98/79/EEC and 90/385/EEC.

We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova.

*Your Sincerely*

*Mgr. Jiri Lacina, MBA*
*Managing director*

GETINGE
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MEMBER OF THE GETINGE GROUP

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DIČ: 2024123464
Spoločnosť zapísaná v Obchodnom registri
Okresného súdu Bratislava I, oddiel: Sro, vložka číslo: 99838/B
Konateľ: Mgr. Jiří Lacina, MBA
Bankové spojenie: Commerzbank AG Bratislava
Číslo účtu:: 70081547/8050

**Ing. Lena Pavlovičová**
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