# **Certificate of Registration**



This is to certify that the quality management system of

# SMITHS MEDICAL CZECH REPUBLIC a.s.

Olomoucká 306, 753 01 Hranice, Czech Republic

has been assessed and registered by AMTAC Certification Services Limited as conforming to the requirements of:

EN ISO 13485:2012

The quality management system is applicable to:

The design, assembly, manufacture, packaging and supply of:

Obstetrics and Gynaecology Devices and Accessories,
Interventional Imaging Devices and Accessories,
Oxygen & Humidity Management Devices,
Pain Management Devices and Accessories,
Invasive Patient Pressure Monitoring Devices and Accessories,
Tracheostomy Devices,
Disposable Infusion Devices,
Suction Catheters Devices,
Intubation Systems Devices.

Certificate Number: 1201-04 B

Initial Certification Date: 10 January 2014
Certificate Effective Date: 22 May 2017
Certificate Expiry Date: 28 February 2019





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Brian Johnson

AMTAC Certification Services Limited, Milton Keynes, UK
This certificate is the property of AMTAC Certification Services Ltd

In the issuance of this certificate, Intertek assumes no liability to any party other than to the Client, and then only in accordance with the agreed upon Certification Agreement. This certificate's validity is subject to the organization maintaining their system in accordance with Intertek's requirements for systems certification. Validity may be confirmed via email at certificate.validation@intertek.com or by scanning the code to the right with a smartphone. AMTAC Certification Services Limited is owned by AMTAC Certification Services Holdings Limited, which is a wholly owned subsidiary of Intertek UK Holdings Limited. AMTAC Certification Services Limited is an accredited body registered under UKAS with the identification number of 061. In the issuance of this certificate, AMTAC assumes no liability to any party other than to the Client and then only in accordance with the agreed Terms and Conditions.



The certificate remains the property of Intertek, to whom it must be returned upon request.

## Certificat de Înregistrare



Se certifică prin prezenta că sistemul de management al calității al

#### SMITHS MEDICAL CZECH REPUBLIC a.s.

Olomoucká 306, 753 01 Hranice, Republica Cehă

a fost evaluat si înregistrat de AMTAC Certification Services Limited ca fiind conform

### EN ISO 13485:2012

Sistemul de management al calității este aplicabil pentru: Proiectarea, asamblarea, fabricarea, ambalarea si furnizarea de:

Dispozitive și Accesorii pentru Obstetrică și Ginecologie, Dispozitive și Accesorii Intervenție Imagistică, Dispozitive de Management al Oxigenului si Umiditătii, Dispozitive și Accesorii de Management al Durerii, Dispozitive si Accesorii Invazive de Monitorizare a Tensiunii Pacientului.

Dispozitive Traheotomie, Dispozitive de Unică Folosintă pentru Injectii, Dispozitive Catetere Aspirare. Sisteme de Dispozitive de Intubare.

Certificat Număr:

Data Initială a Certificării: Data Efectivă a Certificatului: Data Expirării Certificatului:

1201-04 B

10 Ianuarie, 2014 22 Mai 2017 28 Februarie 2019



undere față de altă Parte în afară de Client, și aceasta, numai în c



Brian Johnson AMTAC Certification Services Limited, Milton Keynes, UK Acest Certificat este proprietatea AMTAC Certification Services Ltd

in entende a certification and entended relative about intended and an electric and a certification and extended and exten rea acestui certificat, AMTAC nu-si asumă nicio re acreditat înregistrat la UKAS cu numărul de identificare 061. În emit decât Clientul, si acea

nai în conformitate cu Termenii și Condițiile agreate. Certificatul rămâne proprietatea Intertek, căreia îi trebuie returnat la c CT-ISO 9001:2008-LIKAS-EN-LT-P-04 ian 12

Subsemnata MUSUROIA MIRELA, traducator autorizat de Ministerul Justiției, certific exactitatea acestei traducerii cu textul înscrisului original în limba engleza, ce a fost vizat de mine.



