

MED/CERT

Certificate

The Certification Body

MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
Pilatuspool 2 – 20355 Hamburg – Germany

herewith confirms that the company

Sensatronic GmbH
Alter Holzhafen 19 – 23966 Wismar
Germany

has introduced and applies a Quality Management System in the area of

Design, manufacture, final inspection and service of
blood warmer, flow- and temperature sensors
as well as corresponding analysis systems

A Quality Audit demonstrated compliance of the Quality Management System with

EN ISO 13485:2012 + AC:2012

The certification assumes that the company is applying and maintaining its
Quality Management System according to the above given standard.

The license of certification is subject to surveillance by MEDCERT.

This certificate is valid until: 07 August 2018
Hamburg, 20 August 2013

Process No.: QS - 2697
Certificate No.: 2697GB438130820



MEDCERT Certification Body
(Markus Bianchi)



Akkreditiert durch
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln
und Medizinprodukten
ZLG-ZQ-983.99.02-46



EC Certificate of Conformity

The Notified Body

MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
Pilatuspool 2 – 20355 Hamburg – Germany

herewith confirms that the company

Sensatronic GmbH
Alter Holzhafen 19 – 23966 Wismar
Germany

has introduced and applies a Quality Management System
for the products / product categories

Blood warmer, flow- and temperature sensors
as well as corresponding analysis systems

An Audit demonstrated compliance of the Quality Management System with

Annex II
excluding section (4)

of the **Council Directive 93/42/EEC concerning Medical Devices.**

The certification assumes that the company is applying and maintaining its Quality Management System according to the above given annex. The license of certification is subject to surveillance by MEDCERT.

This certificate is valid until: 07 August 2018
Hamburg, 20 August 2013

Process No.: QS - 2697
Certificate No.: 2697GB410130820
MEDCERT Identification No.: 0482

MEDCERT Certification Body
(Markus Bianchi)



Akkreditiert durch
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln
und Medizinprodukten
ZLG-ZQ-983.94.13