



Certificate

The Certification Body

MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
Vorsetzen 35 – 20459 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, emergency and transport ventilators,
flow-, pulse oximetry- and temperature sensors
as well as corresponding measuring systems and
Foley catheters with temperature sensor**

A Quality Audit demonstrated compliance of the Quality Management System with

EN ISO 13485:2003 + AC:2007

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 from 07 August 2008 until 07 August 2013

Hamburg, 31 July 2008

Process No.: QS - 2697

Certificate No.: 2697GB431080731

A handwritten signature in blue ink, appearing to read "Frank Wilmerstädt".

MEDCERT Certification Body
(Frank Wilmerstädt)



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
Vorsetzen 35 – 20459 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 category

**Blood warmer, emergency and transport ventilators,
flow-, pulse oximetry- and temperature sensors
as well as corresponding measuring systems,
Foley catheters with temperature sensor**

An Audit demonstrated compliance of the Quality Management System with

Annex II

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 from 07 August 2008 until 07 August 2013

Hamburg, 31 July 2008

Process No.: QS - 2697

Certificate No.: 2697GB410080731

MEDCERT Identification No.: 0482

A handwritten signature in blue ink, appearing to read "Frank Wilmerstädt".

MEDCERT Certification Body
(Frank Wilmerstädt)



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Zentralstelle der Länder
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ZLG-ZQ-983.94.13