

Certificate

The Certification Body

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

herewith confirms that the company

**Ascamed GmbH
Siemensstraße 19
06449 Aschersleben
Germany**

has introduced, applies and maintains a Quality Management System **for the reprocessing of medical devices, including the classification „critical C“**, according to the recommendations of the Commission for Hospital Hygiene and Infection Prevention (KRINKO) at the Robert Koch-Institute (RKI) and Federal Institute for Drugs and Medical Devices (BfArM) regarding the „Requirements on the Hygiene at the Reprocessing of Medical Devices“ (2012).
(Products as per attachment)

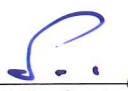
The compliance of the Quality Management System with the requirements of the below mentioned standard was verified by an audit:

DIN EN ISO 13485:2012

This certificate is valid until: 26 March 2018

Report No.: 4943FS09F
Process No.: QS – 4943
Certificate No.: 4943GB437150619

Hamburg, 19 June 2015



MEDCERT Certification Body
(Dr. Andreas Schich)

**DAkkS**
Deutsche
Akkreditierungsstelle
D-ZM-19630-04-00

**Attachment
Certificate
QS - 4943**

This attachment is valid only in connection with certificate No: 4943GB437150619

Electrical catheters without lumen	EP ablation catheter EP ablation catheter, magnetically steerable EP diagnostic catheter EP oesophageal probe Pacing electrode, temporary EP diagnostic catheter, steerable Renal ablation catheter, steerable Catheter for vascular vein surgery Diagnostic ultrasound catheter
Electrical catheters with lumen	EP ablation catheter, irrigated EP ablation catheter, irrigated, magnetically steerable Catheter for vascular vein surgery with lumen Pressure volume catheter, irrigated Diagnostic ultrasound catheter, with lumen
Catheters with lumen	Angiographic catheter Guiding catheter Introducer sheath Introducer sheath, steerable
Connection cable	EP extension cable
Cannulae	Transseptal needle Transseptal needle, electrical
Light transmitting instruments	Optical fibre, ophthalmology
Endoscopes	Endoscopes, rigid Endoscopes, flexible Endoscopic fibre

Hamburg, 19 June 2015



MEDCERT Certification Body
(Dr. Andreas Schich)