DAKKS CRT2 / 10.



CERTIFICATE

No. Q1N 15 05 39212 017

Holder of Certificate: Osypka Medical GmbH

Albert-Einstein-Strasse 3

12489 Berlin GERMANY

Facility(ies):

Osypka Medical GmbH

Albert-Einstein-Strasse 3, 12489 Berlin, GERMANY

Certification Mark:



Scope of Certificate:

Design and Development, Production and Distribution of Hemodynamic Monitoring Equipment, External Pacemakers, Pacing System Analyzers, Patient Cables and Sales of Disposables (ECG adhesive Electrodes, Device Holders, Interface Cables) for the areas of Cardiovascular and General Surgery,

Emergency and Intensive Care, Cardiology and Neonatology

Applied
Standard(s):

EN ISO 13485:2012 + AC:2012

Medical devices - Quality management systems -

Requirements for regulatory purposes (ISO 13485:2003 + Cor. 1:2009) DIN EN ISO 13485:2012

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.:

713059313

Valid from:

2015-06-01

Valid until:

2018-05-31

H.- N.

Date, 2015-05-26

Hans-Heiner Junker

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