DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

Product Service

Certificate

No. Q5 037893 0040 Rev. 01

Holder of Certificate: **OncoTherm Kft.**
Gyár utca 2
2040 Budaörs
HUNGARY

Facility(ies):
OncoTherm Kft.
Gyár utca 2, 2040 Budaörs, HUNGARY

OncoTherm GmbH
Belgische Allee 9, 53842 Troisdorf, GERMANY

Certification Mark:

Scope of Certificate: **Design and development, production, distribution, installation and service of Electro-Hyperthermia Units for Oncology**

Applied Standard(s):
EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

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.: 713125409

Valid from: 2018-10-16
Valid until: 2021-10-11

Date, 2018-10-16

Stefan Preiß

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

A4 / 07.17

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT
TÜV SÜD