EC Certificate

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60113456 0001

Report No.: 21253381 001

Manufacturer:
RAPID Biomedical GmbH
Kettelerstr. 3-11
97222 Rimpar
Deutschland

Products:
RF coils for magnetic resonance systems for medical diagnostics

Replaces Certificate, Registration No.: HD 60109637 0001

Expiry Date: 2021-09-05

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2016-09-06

Date: 2016-09-05

Notified Body

Dipl.-Ing. D. Meier

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.