



Certificate of CE-Registration

This is to certify that, in accordance with the Medical Device Directive 93/42/EEC, Medical Device Safety Service GmbH (MDSS) agrees to perform all duties and responsibilities as the Authorized Representative for:

Hartalega Sdn. Bhd.
C-G-9, Jalan Dataran SD1, Dataran SD
PJU9, Bandar Sri Damansara,
52200 KUALA LUMPUR

Facility:
Hartalega Sdn. Bhd.
No 7, Kawasan Perusahaan Suria,
Bestari Jaya,
45600 Selangor Daril Ehsan
MALAYSIA

as stipulated and demanded by the aforementioned Directive. The German Competent Authority has allocated the medical devices of the Manufacturer registration numbers as foreseen in:

Annex A dated November 13, 2013

The Manufacturer has provided MDSS with the appropriate Declaration(s) of Conformity confirming that the medical devices fulfill the applicable requirements of Directive 93/42/EEC. In compliance with German law, a safety officer has been appointed for Germany.

2013-11-13

Julia Warnemann
Senior Manager Registration
MDSS GmbH