Certificate of CE-Registration

MDSS Medical Device Safety Service

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:

Sumitomo Bakelite Co., Ltd.
2-5-8, Higashi-Shinagawa
Shinagawa-Ku
TOKYO
140-0002
JAPAN

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 21, 2012

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.

2012-11-21

Ludger Möller
-President-
MDSS GmbH

Annex A dated November 21, 2012
Sumitomo Bakelite Co., Ltd.

Notified Medical Device & UMDNS Description	UMDNS Code	Risk Class	Cat. Code	Registration Number	NB No. / NB Certificate No.	NB Cert. Valid Until YYYY-MM-DD
Retractors, Cardiac	13-379	IIa	10	DE/CA09/0170/1643-A2	0123/G1 12 09 59002 004	2016-06-22
Tentacles						
MD-27310 MD-27310-ZZZ						
Tubes, Esophageal	14-195	IIa	10	DE/CA09/0170/4207	0123/G1 12 09 59002 004	2016-06-22
Flexibel Overtube™						
MD-48518, MD-48618, MD-48718						
Forceps, Electrosurgical	11-502	IIb	10	DE/CA09/0170/4204	0123/G1 12 09 59002 004	2016-06-22
SB knife™						
MD-47704, MD-47706, MD-47703						
Caps	16-081	IIa	10	DE/CA09/0170/4206	0123/G1 12 09 59002 004	2016-06-22
SB Hood™						
MD-47910, MD-47920, MD-47930, MD-47940						

MDSS
Medical Device Safety Service