Certificate Of Origin

medentis medical

Herewith we medentis medical GmbH declare that the following medical devices:

- ICX-templant implants
- ICX-templant abutments
- ICX-templant healing caps and cover screws
- ICX-templant drills
- ICX-templant accessories and tools

are manufactured in terms of the European Medical Device Directive (MDD) 93/42/EEC on our manufacturing site located at Gartenstrasse 12, 53507 Dernau, Germany.
Thus, abovementioned goods are considered as German origin.
Following standards and rules are implemented during design, development and manufacture of abovementioned products:

- EN ISO 9001:2008
- EN ISO 13485:2003/AC:2009
- Provisions of Medical Device Directive 93/42/EEC
- EN 980:2008
- EN ISO 11137-1:2006
- EN ISO 11137-2:2007/AC:2009
- DIN EN ISO 11137-3:2006-07
- EN ISO 14971:2009
- EN ISO 10993-1:2009
- EN ISO 10993-3:2009
- EN ISO 10993-5:2009
- EN ISO 10993-6:2009
- EN ISO 10993-10:2009
- EN ISO 10993-11:2009
- DIN EN ISO 14801:2008-02
- EN ISO 11607-1:2009
- EN ISO 11607-2:2006
- DIN ISO 5832-2:2008
- EN ISO 17664:2004
- EN ISO 17665-1:2006
- DIN EN ISO 1797-1:2009-8
- DIN EN ISO 3823-1:1998
- EN 1639:2004
- DIN EN 10088-1:2005-09
- DIN ISO 5832-2:2008
- DIN ISO 5832-3:2000-08

Dernau, 13.01.2011

Alexander Scholz,
Managing Director medentis medical GmbH

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