EC Declaration of Conformity for medical devices

(as defined by directive for medical devices 93/42/EEC, MDD 2007, Annex VII)

DeMeTec GmbH

Lützelwiesen 5, 35428 Langgöns (Germany)

We hereby declare, that the product

Medical Parallel Port Isolation – PPI Version 1.4

was manufactured in harmony with the technical documentation as defined by Annex VII, section 3 of the medical device directive and that it corresponds to the requirements of the following directive:

Medical Device Directive 93/42/EEC

Meeting the following standards: **IEC 60601-1:2005 (DIN EN 60601-1:2006)**
IEC 60601-1-2:2007 (DIN EN 60601-1-2:2007)

As well the following guideline will be followed:

Directive 2002/95/EC (RoHS)

In compliance with the national law: **Electrical and Electronic Equipment (WEEE)**

CE

Langgöns, 2012-05-31

Harald Hellmann

Manager
Head of Development Department

Majet Mahali

Quality Management Officer
Regulatory Affairs