CyDen

EC Declaration of Conformity

CE

0086

We

CyDen Ltd
Technium 2, Kings Road
SA1 8PH, Wales, UK

declare that the products 'IFLTM i200+ System' and 'IFLTM i300 System' are identical in both electrical and electronic design, to which this declaration relates, conforms with the Essential Requirements of the Medical Device Directive 93/42/EEC:1993 and with the following standards in accordance with the provisions of the Essential Requirements of the Medical Devices Directive:

BS EN ISO 9001:2000	Quality Management System
BS EN ISO 13485:2003	Medical Quality management System (excl Design)
EN 60601-1-1:2001	Medical electrical equipment – Part 1, Safety requirements for Medical Electrical Systems.
EN 60601-1-2:2001	Medical electrical equipment – Part 1, Safety 2 requirements for Medical Electromagnetic Compatibility.
EN 6100-3-2:2000	Electromagnetic Compatibility – Harmonic emissions.
EN 6100-4-2	Electromagnetic Compatibility – Immunity.

I hereby declare that the equioment named above has been designed to comply with the relevant sections of the above reference specifications. The unit complies with all essential requirements of the Directives. The product has been classified as being a Class IIA Medical Device in accordance with the MDD 93/92/EEC:1993.

Signed by:

Name: Kevin Smith

Position: Operations Director

Place: Swansea, UK

Date: 11 Mar 2008