



EC Certificate
Full Quality Assurance System according to
Medical Devices Directive 93/42/EEC Annex-II Section 3

Certificate Number: 1984-MDD-19-560

We hereby declare that an examination of the under mentioned full quality assurance system has been carried out following the requirements of the national legislation to which the undersigned is subjected, transposing annex II (with the exemption of section 4) of the Directive 93/42/EEC on medical devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive.

Organization:

INFINIUM MEDICAL INC.

12151 62nd St. N. #5 Largo, FL 33773 USA

Product: Patient Monitor

Models: OMNI, OMNI K, OMNI II, OMNI IIK, OMNI III, OMNI EXPRESS, CLEO

The certificate is valid till expiration date, subject to successful completion of periodical surveillance audits. Please contact Kiwa for details.

Report Number: M.5062.01

Expiry Date: 10 January 2022

Kiwa Certification Services Inc. is Notified Body under Council Directive 93/42/EEC concerning medical devices with identification number: 1984

11 January 2019, Istanbul, Turkey

Head of Notified Body