



Product Service

Supplement to Quality System Certificate Q4N 12 05 69803 002

issued by TÜV SÜD PRODUCT SERVICE GMBH on 2012-06-12 to

ELECTRON BEAM SDN. BHD.
Lot 7, Jalan Sungai Pinang 4/3
Taman Perindustrian Pulau Indah (FASA 2)
42920 Port Klang, Selangor
MALAYSIA

for the facility

ELECTRON BEAM SDN. BHD.
Lot 7, Jalan Sungai Pinang 4/3
Taman Perindustrian Pulau Indah (FASA 2)
42920 Port Klang, Selangor
MALAYSIA

The quality system certified as stated above additionally fulfills the applicable requirements of **EN ISO 11137-1: 2006 - Sterilization of health care products – Radiation -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices** - as documented in the audit report no. MYQMH0212004Rev1-721405303 dated 2012-05-16.

The assessment was performed by auditors authorized under TÜV SÜD Product Service GmbH procedures. The audit team included an auditor authorized for sterilization.

This supplement is valid only together with the certificate stated above.

TÜV SÜD PRODUCT SERVICE GMBH
Certification Committee for Medical Devices

Munich, 2012-06-12

TÜV SÜD Product Service GmbH is a Notified Body (identification number 0123) according to Council Directive 93/42/ EEC concerning medical devices.

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