EC TYPE-EXAMINATION CERTIFICATE

Number: 87754TE06

Directive 93/42/EEC on Medical devices, Annex III

(Devices in Class IIb and III)

Manufacturer:

European Medical Contract Manufacturing B.V.

Middenkampweg 17 6545 CH Nijmegen The Netherlands

For the product / product category

C~plug®

Documents, that form the basis of this certificate:

Certification Notice 87754CN, initially dated 1 July 1998

DEKRA hereby certifies that the type of the product(s) falling within the product category mentioned above, fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Council Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments, based on an examination in accordance with Annex III (4) of this Directive.

The necessary information and the reference to the relevant documentation, of the products concerned and the examinations and assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 1 March 2018 Issued for the first time: 1 March 2001 Reissued: 1 March 2015

DEKRA Certification B.V.

drs. G.J. Zoetbrood Managing Director ing. A.A.M. Laan Certification Manager

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