

EC DESIGN-EXAMINATION CERTIFICATE

Directive 93/42/EEC on Medical Devices, Annex II (4)

No. 5-718-204-1206

National Institute for Quality- and Organizational Development
in Healthcare and Medicines

Directorate of Device Testing and Clinical Engineering (EMKI)

certifies that the following manufacturer's

Sanatmetal Ortopédiai és Traumatológiai Eszközök Gyártó Kft.
3300 Eger, Faiskola u. 5.

Hungary

product's

CarBulat™ Hip Prosthesis System

(models listed in the attachment)

design dossier conforms to the requirements of Directive 93/42/EEC on Medical Devices.

Registry number of the report on the examination of the design dossier: **42-4105-2012**

This certificate is valid only together with EC Certificate according to Directive 93/42/EEC on Medical Devices Annex II excluding (4) No. **5-699-200-1111**.

This certificate is valid until: **2016-11-13**

Issued by EMKI as a Notified Body with identification number **1011**.

This certificate is valid only with the attachment.

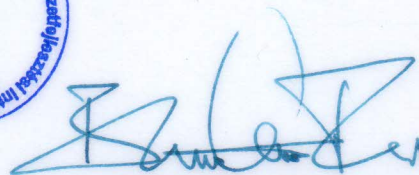
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General Director



Certification Office



EMKI 0822

The authenticity and validity of the certificate is verifiable at EMKI.

Gyógyszerészeti és Egészségügyi Minőség- és Szervezetfejlesztési Intézet
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