

EC CERTIFICATE
Full Quality Assurance System
Directive 93/42/EEC on Medical devices Annex II excluding (4)

No. 5-699-200-1111

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

Directorate of Device Testing and Clinical Engineering (EMKI)

certifies that the manufacturer:

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

for the products / product categories:

Sterile Hip and Knee Prosthesis Systems

applies a quality system which meets the requirements of Directive 93/42/EEC on Medical devices Annex II.

Registry number of the related audit report: **42-012-2009**

This certificate is valid only together with EC Design-Examination Certificates according to Directive 93/42/EEC on Medical devices Annex II (4) No. **5-700-204-1111, 5-701-204-1111, 5-718-204-1206.**

This Certificate is valid until **2016-11-13** supposed that the results of the regular yearly surveillance audits are satisfactory.

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

Issue: 2

First issued: 2011-11-14

Budapest, 2012-06-08




General Director


Certification Office



EMKI 0763

The validity of the certificate is verifiable at EMKI.

Gyógyszerészeti és Egészségügyi Minőség- és Szervezetfejlesztési Intézet
National Institute for Quality- and Organizational Development in Healthcare and Medicines
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