

EC DESIGN-EXAMINATION CERTIFICATE

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

No. 5-809-204-1611

National Institute of Pharmacy and Nutrition
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 concerning medical devices, Annex II.

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. **5-806-200-1611**.


This certificate is valid until: **2021-11-13**

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

This certificate is valid only with the attachment.

Budapest, 2016-11-14


Deputy General Director


Head of EMKI



EMKI 1579

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

Országos Gyógyszerészeti és Élelmezés-egészségügyi Intézet
National Institute of Pharmacy and Nutrition
Eszközminősítő és Kórháztechnikai Igazgatóság
Directorate of Device Testing and Clinical Engineering

H-1051 Budapest, Zrínyi u. 3. Fax: +36 1 886 94 60, Telefon: +36 1 225 27 39
H-1097 Budapest, Albert Flórián út 3/A, E-mail: cert@emki.hu, Web: www.emki.hu



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ATTACHMENT TO EC DESIGN-EXAMINATION CERTIFICATE

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Additional information for Certificate No. 5-809-204-1611

The certificate is valid for the following manufacturing site / facility:

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

The certificate is valid for the following products:

CarBulat™ Hip Prosthesis System

Class: III

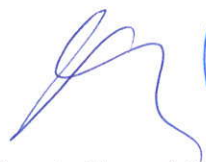
Catalogue number	Description	Size
411600002	CarBulat™ stem	0
411600012	CarBulat™ stem	1
411600022	CarBulat™ stem	2
411600032	CarBulat™ stem	3
411600042	CarBulat™ stem	4
411600052	CarBulat™ stem	5
411600062	CarBulat™ stem	6
411600072	CarBulat™ stem	7
412100280	Femoral head	28/M (0)
412100283	Femoral head	28/L (+3)
412100285	Femoral head	28/XL (+5)
412100288	Femoral head	28/XXL (+8)
412100289	Femoral head	28/XXXL (+12)
412103320	Femoral head	32/S (-3)
412100320	Femoral head	32/M (0)
412100323	Femoral head	32/L (+3)
412100325	Femoral head	32/XL (+5)
412100328	Femoral head	32/XXL (+8)
412100329	Femoral head	32/XXXL (+12)

The product list is kept by EMKI under No. 42-4105-2012.

Issue: 1

Date: 2016-11-14

First issued: 2016-11-14



Deputy General Director




Head of EMKI



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