144969-19-11-06

EC CERTIFICATE

Full Quality Assurance System

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

CE Certiso Ltd. (NB 2409) certifies that the following manufacturer's quality management system concerning to the listed devices and device categories meets the requirements of the related requirements of the directive.

Name of the manufacturer:

Sanatmetal Ortopédiai és Traumatológiai Eszközöket Gyártó Kft.

Headquarters: **3300 Eger, Faiskola út 5.**

Manufacturing plant: **Sanatmetal CIS**
249030 Russia, Kaluga region, Obninsk, Kievskoe shosse, 92

Scope:

Knee and Hip implant systems, Ceramic ball head

This certificate is valid only with the annexes, in case of successfully conducted annual surveillance audits.

ID number of the related audit report: **181-CE-190109**

Digitally signed by Grabazei Alexandru
Date: 2021.09.01 14:38:12 EEST
Reason: MoldSign Signature
Location: Moldova

Issue: 1
Issued: 06 November 2019
First issued: 06 November 2019
Start date of certified status: 06 November 2019

Expires:
25 May 2024

Valter PAPP, Dr.
General Manager

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NB2409
Notified Body

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NB ID number: 2409

The certificate covers the following devices:

Description of the device	Type	Intended use	Model	Risk class
knee prosthesis system	Sanat Swing -CR and -PS primer knee prosthesis systems	knee arthroplasty	see product list	III.*
	Sanat Swing – CC revision knee prosthesis system			
hip prosthesis system	Pannon, Sanat-E, Sanat-M primer hip prosthesis systems	hip arthroplasty	see product list	III.*
	Sanat-R 2 revision hip prosthesis system			
ceramic ball head	ceramic ball head	ceramic head to hip prosthesis	see product list	III.*
	ceramic ball head with adaptor			

*In case of devices in Class III, this certificate independently does not authorize the manufacturer for the use of CE mark on the devices. Detailed product list was issued as annex of the relevant design evaluation certificate.

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