

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

CE Certiso Ltd. (NB 2409) certifies that the design of the device concerning to the listed devices and device categories conforms to the requirements of the directive.

Name of the manufacturer:

**Sanatmetal Ortopédiai és Traumatológiai
Eszközök Gyártó Kft.**

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

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

Scope:

Ceramic ball head

The certificate covers the following devices:

Description of the device	Type	Intended use	Model	Risk class
ceramic ball head	ceramic ball head	ceramic head to hip prosthesis	see product list	III.*
	ceramic ball head with adaptor			

This certificate is valid only with the annexes and the system certificate No. **144969-19-11-06**, in case of successfully conducted annual surveillance audits.

ID number of the related design examination report: 181-G3-190109

Issue: 1

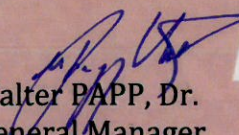
Issued: 6 November 2019

First issued: 6 November 2019

Start date of certified status: 6 November 2019

Expires:

25 May 2024

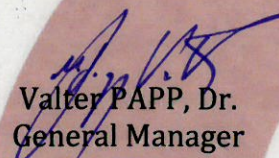

Valter PAPP, Dr.
General Manager

The certificate covers the following devices:

Tételkód / Code	Megnevezés	Description	Méret / Size
412200280	Kerámia fej	Ceramic head	28/M (0)
412200283	Kerámia fej	Ceramic head	28/L (+3.5)
412200320	Kerámia fej	Ceramic head	32/M (0)
412200323	Kerámia fej	Ceramic head	32/L (+3.5)
412200327	Kerámia fej	Ceramic head	32/XL (+7)
412200360	Kerámia fej	Ceramic head	36/M (0)
412200363	Kerámia fej	Ceramic head	36/L (+3.5)
412200367	Kerámia fej	Ceramic head	36/XL (+7)
412200400	Kerámia fej	Ceramic head	40/M (0)
412200403	Kerámia fej	Ceramic head	40/L (+3.5)
412200407	Kerámia fej	Ceramic head	40/XL (+7)
412203280	Kerámia fej	Ceramic head	28/S (-3.5)
412203320	Kerámia fej	Ceramic head	32/S (-3.5)
412203360	Kerámia fej	Ceramic head	36/S (-3.5)
412203400	Kerámia fej	Ceramic head	40/S (-3.5)
412220000	Fém adapter	Metal adaptor	M (0)
412220004	Fém adapter	Metal adaptor	L (+4)
412220007	Fém adapter	Metal adaptor	XL (+7)
412220013	Fém adapter	Metal adaptor	S (-3)
412220028	Kerámia fej adapterhez	Ceramic head for adaptor	28 mm
412220032	Kerámia fej adapterhez	Ceramic head for adaptor	32 mm
412220036	Kerámia fej adapterhez	Ceramic head for adaptor	36 mm
412220040	Kerámia fej adapterhez	Ceramic head for adaptor	40 mm

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