

EC Design Examination Certificate

SQS as a conformity assessment body identification number 1250 herewith declares that for the organisation

Stemcup Medical Products AG

Aargauerstrasse 180
8048 Zürich
Switzerland

a design examination has been carried out according to:

ANNEX II

Directive 93/42/EEC

This approval is based on the result of a design examination documented in the report dated March 30, 2020.

The scope of validity covers the products

Hip stem	SCS/SCL/SCR, BSC, BreXis, Stelia
Hip cup	BSC standard/pressfit, BSC pressfit Ti/HA, ISC pressfi XentraX Screwcup, Benefit Screwcup SSC Screwcup, BSC Macro, BSC Macro Ti/HA
Ballhead	CoCr, CrNi, Ceramic
Bipolarhead	CoCr, CrNi
Insert	Xonit X-PE-Insert, Xonit-E X-PE-Insert PE-Insert, Ceramic-Insert

The following CE label can be applied to these products mentioned in the Appendix of this certificate

CE 1250

For marketing of these products an additional Annex II (without section 4) certificate is mandatory.

A condition for the validity of this certificate is a regular examination in accordance with Annex II.5 of the Directive 93/42/EEC.

Reg. no. 37988

Validity 27.04.2020 – 25.05.2024
Issue 27.04.2020

Approved Medical Responsible
27.04.2020

F. Müller, CEO SQS

D. Taddeo, Medical Responsible



Appendix to the EC Design Examination Certificate

ANNEX II

Directive 93/42/EEC

This Appendix is valid only in connection with the following certificate:

Registration Number 37988

Validity from April 27, 2020 up to and including May 25, 2024

This approval includes the following Medical Device/s:

Class III

- Stelia Stem standard (size 01–10)
- Stelia Stem lateral (size 1–9)
- Stelia Stem standard basic (size 01–10)
- Stelia Stem lateral basic (size 1–9)
- Stelia Stem standard Ti/HA coated (size 01–10)
- Stelia Stem lateral Ti/HA coated (size 1–9)
- BreXis Short Stem standard (size 0–10)
- BSC Stem cemented (size 0–6 r+l)
- BSC Stem uncemented (size 0–7 r+l)

- SCS Stem (size 01–10) TiVa
- SCL Stem (size 1–9) TiVa
- SCR Stem (size 3–11) TiVa

- SCS-Stem (size 01–10) TiNb
- SCL-Stem (size 1–9) TiNb
- SCR-Stem (size 3–11) TiNb

- SCS-Stem (size 01–10) TiNb-Ti/HA coated
- SCL-Stem (size 1–9) TiNb-Ti/HA coated
- SCR-Stem (size 3–11) TiNb-Ti/HA coated

- BSC cup standard (size 46–66)
- PE-Insert standard (size 28, 32)
- PE-Insert dysplasia (size 28, 32)
- Ceramic-Insert BioloX forte (size 28, 32)
- Ceramic-Insert BioloX delta (size 28, 32, 36)
- BSC Macro cup (closed, 3 holes, 3 holes closed, size 46–66)
- BSC Macro cup Ti/HA coated (closed, 3 holes, 3 holes closed, size 46–66)
- BSC Macro cup clusterhole (size 50–66)
- BSC Macro cup clusterhole Ti/HA coated (size 50–66)
- BSC Macro cup multihole (size 46–66)
- BSC Macro cup multihole Ti/HA coated (size 46–66)



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- BSC cup pressfit (closed, 3 hole, 3 hole closed, size 46–66)
- BSC cup pressfit Ti/HA coated (closed, 3 hole, 3 hole closed, size 46–66)
 - PE-Insert standard (size 28, 32)
 - PE-Insert dysplasia (size 28, 32)
 - Xonit X-PE-Insert standard (size 28, 32, 36, 40)
 - Xonit X-PE-Insert dysplasia (size 28, 32, 36, 40)
 - Xonit-E X-PE-Insert standard (size 28, 32, 36, 40)
 - Xonit-E X-PE-Insert dysplasia (size 28, 32, 36, 40)
 - Ceramic-Insert BioloX forte (size 28, 32)
 - Ceramic-Insert BioloX delta (size 28, 32, 36, 40)
- ISC cup pressfit (size 46-66)
 - PE-Insert standard (size 28, 32)
 - PE-Insert dysplasia (size 28, 32)
 - Ceramic-Insert BioloX forte (size 28, 32)
 - Ceramic-Insert BioloX delta (size 28, 32, 36, 40)
- XentraX Screwcup (size 46-68)
 - PE-Insert standard (size 28, 32)
 - PE-Insert dysplasia (size 28, 32)
 - Xonit X-PE-Insert standard (size 28,32,36,40)
 - Xonit X-PE-Insert dysplasia (size 28,32,36,40)
 - Xonit-E X-PE-Insert standard (size 28,32,36,40)
 - Xonit-E X-PE-Insert dysplasia (size 28,32,36,40)
 - Ceramic-Insert BioloX forte (size 28, 32)
 - Ceramic-Insert BioloX delta (size 32, 36, 40)
- Benefit Screwcup (size 46-68)
 - PE-Insert standard (size 28, 32)
 - PE-Insert dysplasia (size 28, 32)
 - Ceramic-Insert BioloX forte (size 28, 32)
 - Ceramic-Insert BioloX delta (size 28, 32, 36, 40)
- SSC Screwcup (size 45 -72)
 - PE-Insert standard (size 28, 32)
 - PE-Insert dysplasia (size 28, 32)
 - Xonit X-PE-Insert standard (size 28,32,36,40)
 - Xonit X-PE-Insert dysplasia (size 28,32,36,40)
 - Xonit-E X-PE-Insert standard (size 28,32,36,40)
 - Xonit-E X-PE-Insert dysplasia (size 28,32,36,40)
 - Ceramic-Insert BioloX forte (size 28, 32)
 - Ceramic-Insert BioloX delta (size 28, 32, 36, 40)



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- Ballhead CoCr (size 22, 28, 32, 36, 40)
- Ballhead CrNi (size 28, 32)
- Bipolarhead CoCr (size 39-65)
- Bipolarhead CrNi (size 39-65)
- Ballhead Ceramic BioloX Forte (size 28-36) and Delta (size 28-40)
- Ballhead Ceramic Stemox (size 28-32)

Appendix Issue: April 27, 2020



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D. Taddeo, Medical Responsible

