

SQS as a conformity assessment body identification number 1250 herewith certifies the organisation

**Stemcup Medical Products AG**  
**Aargauerstrasse 180**  
**8048 Zürich**  
**Switzerland**

the use of a quality assurance system in its design, development, manufacturing and distribution which fulfills the requirements set out in:

## ANNEX II

## Directive 93/42/EEC (without section 4)

This approval is based on the report dated April 7, 2020.

The scope of validity covers the products

**Hip stem, Hip cup,  
Ballhead CoCr, CrNi and Ceramic,  
Bipolar head CoCr, CrNi  
Instruments for hip implants,  
INWIFIX® Plate Insert  
MOP™-Trochanteric Plate**

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

**CE 1250**

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. 30816

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



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Swiss Association for Quality  
and Management Systems (SQS)  
Bernstrasse 103, 3052 Zollikofen, Switzerland



## ANNEX II

## Directive 93/42/EEC (without section 4)

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

Registration Number 30816

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

**This approval includes the following Medical Device/s:**

Class IIa

- Instruments for hip implants

Class IIb

- Cancellous Bone Screws
- Corticalis Screws
- INWIFIX® Plate Insert
- MOP™-Trochanteric Plate

Class III

- Hip stem                    BSC, BreXis, Stelia, SCS/SCL/SCR – TiNb, TiNb-Ti/HA coated, TiVa
- Hip cup                    BSC standard/pressfit, ISC pressfit  
XentraX Screwcup  
Benefit Screwcup  
SSC Screwcup  
BSC Macro
- Ballhead                    BSC pressfit Ti/HA  
CoCr, CrNi  
Bipolarhead CoCr, CrNi
- Ceramic Ballhead        Biolox Forte and Delta, Stemox
- Insert                        Xonit X-PE-Insert  
Xonit-E X-PE-Insert  
PE-Insert  
Ceramic-Insert

Appendix Issue: April 27, 2020

