EC-Certificate

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 May 11, 2018.

The scope of validity covers the products

Hip stem, Hip cup
Ballhead CoCr and Ceramic
Instruments for hip implants
Fixateur Fix-Ex-R
Inwifix Plate Insert

The following CE label can be applied to the 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 01.08.2018 – 31.07.2021
Issue 19.11.2019

Approved Medical Responsible
05.06.2018

F. Müller, CEO SQS

D. Taddeo, Medical Responsible

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

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Swiss Made

Partner of IQNet

4174_2/June 2019/Version 2.0

Appendix to the EC-Certificate

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 August 1, 2018 up to and including July 31, 2021

This approval includes the following Medical Devices:

Class IIa
– Instruments for hip implants

Class IIb
– Fixateur Fix-Ex-R
– Cancellous Bone Screws
– Corticalis Screws
– Inwifix Plate Insert

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 BSC pressfit Ti/HA
– Ballhead	CoCr
– Ceramic Ballhead	Biolox Forte and Delta, Stemox
– Insert	Xonit X-PE-Insert Xonit-E X-PE-Insert PE-Insert Ceramic-Insert

Appendix issue date: November 19, 2019

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