



Certificate

SQS herewith certifies that the company named below has a management system which meets the requirements of the standard specified below.



MPS Precimed SA
Chemin du Long-Champ 95
2504 Biel-Bienne
Switzerland

Scope of certification

The entire company

Field of activity

**Design, manufacturing and distribution
of instruments for surgery**

Normative base

EN ISO 13485:2016 **Medical devices –
Quality Management System**

Validity 31.07.2017 – 30.07.2020
Issue 12.04.2018

Reg. no. 40115

X. Edelman, President SQS

F. Müller, CEO SQS



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



Swiss Made



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

MPS Precimed SA
Chemin du Long-Champ 95
2504 Biel-Bienne
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 result of the audit documented in the report dated June 12, 2017.

The scope of validity covers the products

Instruments for surgery

The following CE label can be applied to these products/the product 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.

Validity 31.07.2017–30.07.2020
Issue 12.04.2018

Reg. no. 41653
Approved Medical Responsible
07.12.2017



F. Müller, CEO SQS



D. Taddeo, Medical Responsible



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ANNEX II

Directive 93/42/EEC (without section 4)

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

Registration Number 41653

Validity from July 31, 2017 up to and including July 30, 2020

This approval includes the following Medical Device/s:

Class IIa

Carbon offset reamer handle with clip

Carbon offset reamer handle without clip

Carbon offset reamer handle dual coupling

Straight reamer handle dual coupling

Navigated carbon offset reamer handle

Intramedullary reamer

Reamer

Drill

T18198-U-joint chain dual coupling for carbon offset reamer handle

T18199-U-joint chain with clip for carbon offset reamer handle

T18200-U-joint chain without clip for carbon offset reamer handle

Appendix established December 7, 2017



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