

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

MPS Precimed SA
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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 report dated May 28, 2020.

The scope of validity covers the products

Instruments for surgery

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. 41653

Validity 24.06.2020–25.05.2024
Issue 24.06.2020

Approved Medical Responsible
24.06.2020



F. Müller, CEO SQS



D. Taddeo, Medical Responsible



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 June 24, 2020 up to and including May 25, 2024

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 Issue: June 24, 2020

