

Declaration of Conformity

Manufacturer Name and Address: MPS Precimed SA
 Chemin du Long-Champ 95
 2504 Biel-Bienne
 Switzerland
 Phone: +41 32 344 92 00
 Fax: +41 32 344 92 92

Product Family: Reamer Handles

Product(s):

| Product Ref. | Product Description |
|-------------------------|--|
| T17705 rev. D | Carbon offset reamer handle AO with clip |
| T17725 rev. D | Carbon offset reamer handle Stryker / Zimmer-Hall with clip |
| T17726 rev. D | Carbon offset reamer handle Hudson with clip |
| T17727 rev. D | Carbon offset reamer handle AO |
| T17728 rev. D | Carbon offset reamer handle Stryker / Zimmer-Hall |
| T17729 rev. D | Carbon offset reamer handle Hudson |
| T17838 rev. B | Carbon offset reamer handle AO |
| T17839 rev. B | Carbon offset reamer handle Stryker / Zimmer-Hall |
| T17874 rev. C | Carbon offset reamer handle Stryker / Zimmer-Hall dual coupling |
| 39 T17875 rev. C | Carbon offset reamer handle AO dual coupling |
| T17876 rev. C | Carbon offset reamer handle Hudson dual coupling |
| T18069 rev. B | Carbon offset reamer handle Stryker / Zimmer-Hall with clip |
| 40 T17780 rev. A | Straight reamer handle AO dual coupling |
| T17781 rev. A | Straight reamer handle Hudson dual coupling |
| T17782 rev. A | Straight reamer handle Stryker / Zimmer-Hall dual coupling |
| T18201 rev. C | Carbon offset reamer handle Stryker / Zimmer-Hall dual coupling |
| T18198 rev. B | U-joint chain dual coupling for carbon offset reamer handle |
| T18199 rev. B | U-joint chain with clip for carbon offset reamer handle |
| T18200 rev. B | U-joint chain for carbon offset reamer handle |
| T18254 rev. B | Straight reamer handle Stryker / Zimmer-Hall dual coupling |
| T18009 rev. D | Navigated carbon offset reamer handle AO parking coupling |
| T18055 rev. D | Navigated carbon offset reamer handle Hudson parking coupling |
| T18056 rev. D | Navigated carbon offset reamer handle Stryker / Zimmer-Hall parking coupling |
| T18380 rev. A | Carbon offset reamer handle Stryker / Zimmer-Hall with parking coupling |
| T18381 rev. A | Carbon offset reamer handle Harris with parking coupling |
| T18382 rev. A | Carbon offset reamer handle AO with parking coupling |

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Classification: Class I per Annex IX of the MDD 93/42/EEC, Rule
 Class IIa per Annex IX of the MDD 93/42/EEC, Rule 9

Conformity Assessment Procedure: MDD 93/42/EEC, Annex VII
 MDD 93/42/EEC, Annex II (with the exception of point 4)

We herewith declare, under our sole responsibility, that the above mentioned products meet all the provisions of the Council Directive 93/42/EEC (amended by Directive 2007/47/EC) which apply to them.

Applied harmonized standards, national standards, or other normative documents:
 EN ISO 13485, EN ISO 14971, EN 1041, EN ISO 15223-1, EN ISO 16061, and EN ISO 17664 (please also refer to the Essential Requirements Checklists for complete list of standards)

Notified Body: SQS
 Bernstrasse 103
 3052 Zollikofen
 Switzerland
 Notified body number: 1250

CE Marking Certificate Number: 41653

DoC valid up to: May 25th, 2024

Place and Date of Issue: Bienne, July 13th, 2020


 Nicola Thibaudeau, MPS Precimed Chief Executive Officer

DoC Revision History:

| Date | Rev. | By | Description of change |
|-------------------------------|------|---------------|---|
| March 25 th , 2015 | 1 | Arnaud BILLOT | Creation of the DoC. |
| April 15 th , 2015 | 2 | Arnaud BILLOT | Adding of the T17727, T17728, T17729, T17838 and T17839 |
| June 08 th , 2015 | 3 | Arnaud BILLOT | Adding of the T17873, T17874, T17875 and T17876 |
| April 26 th , 2016 | 4 | Arnaud BILLOT | Adding of the T18069 Correction of the validity date in accordance with the EC certificate dated on December 17,2015 |

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| May 03 rd , 2016 | 5 | Arnaud BILLOT | Adding of the T17780, T17781 and T17782 |
| May 22 nd , 2017 | 6 | Arnaud BILLOT | Adding of the T18201, T18009, T18055 and T18056 Correction of mistake in the description for T18069 Update of the revision for the T17705, T17725, T17726, T17727, T17728, T17729, T17874, T17875 and T17876 |
| June 14 th , 2017 | 7 | Arnaud BILLOT | Adding of the T18198, T18199 and T18200 |
| July 07 th , 2017 | 8 | Arnaud BILLOT | Renewal of the EC certificate Update of the revision for the T18201 |
| September 20 th , 2017 | 9 | Arnaud BILLOT | Adding of the T18254 |
| September 20 th , 2017 | 10 | Arnaud BILLOT | Adding of the T18009, T18055 and T18056 |
| February 20 th , 2018 | 11 | Arnaud BILLOT | Modification of the address Substitution of standard EN 980 by EN ISO 15223-1 |
| August 28 th , 2019 | 12 | Luis FRAIGEDO | Update the Place and Date of Issue |
| December 16 th , 2019 | 13 | Luis FRAIGEDO | Update of the revision for the T18254, update review T level; T17873 Historiated, Removed T17873 |
| April 23 rd , 2020 | 14 | Luis FRAIGEDO | Adding of the T18380, T18381, T18382 Adding EN ISO 13485, EN ISO 14971 |
| July 13 th , 2020 | 7 | Luis FRAIGEDO | Renewal of the EC certificate (issue 24.06.2020) |