**Document Identification Number:** GPC/DoC/Implants/02/Plates

Issue No.: 01 Revision: 05 Date: 13/09/2017

# EC DECLARATION OF CONFORMITY

**Manufacturer:** GPC MEDICAL LIMITED
PLOT #8, SHUBH PLAZA, M-BLOCK, DDA, LSC,
VIKAS PURI, NEW DELHI 110018 INDIA

**EC REP EC Representative:** JOMISCH
Laan Van Keulen 58, 1827 KW Alkmaar
The Netherlands

**REF Product: Orthopaedic Bone Plates as per Attached Annexure-01**

Batch No.:
Date of Manufacturing: .
Date of Expiry: Inv. No
**Classification:** Class IIb, Rule 8
Confomity Assessmet Route: Annex II (Full Quality Assurance)

1. We declare that our products as mentioned above, comply to the requirements to Medical device Directive 93/42/EEC
2. Company undertakes to manufacture the products as per National/ International Standards and following quality management system as per EN ISO 13485:2012
3. Company authorizes the notified body to carry out necessary inspection and agrees to supply the required information & data/documents from time to time.
4. Company agrees to make available all relevant Documents & Data of the products to the National Authority for a period ending (Fifteen Years) after the last product has been manufactured.
. Company or his authorized representative shall fulfill the obligations imposed by Annex V of Medical Device Directive 93/42/EEC & ensures & declares that the Company's Products shall meet all provision of the directive as applicable.
6. Company undertakes to keep upto date a systematic procedure to review experience gained during post production phase and to implement appropriate means to apply any necessary corrective action taking account of the nature & risk in relation to the product.
7. Company undertakes to notify immediately any malfunction /deterioration of the performance of the device to the appropriate authority and shall recall such devices already placed in the market

CE 2460

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Date: 2019.04.17 08:52:46 EEST
Reason: MoldSign Signature
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CIN No. : U33119DL2004PLC130921

## Standards Applied:

| SN | STANDARD | DESCRIPTION |
|---|---|---|
| 1 | ISO 9001:2008 | Quality management systems -- Requirements |
| 2 | ISO 13485:2003/EN ISO 13485:2012 | Medical devices -- Quality management systems -- Requirements for regulatory purposes |
| 3 | MDD 93/42/EEC as amended by 2007/47/EEC | Medical Device Directive |
| 4 | EN ISO 14971:2012 | Medical devices — Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01) |
| 5 | ISO15223-1:2012 | Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements |
| 6 | EN 980:2008 | Symbols for use in the labelling of medical devices |
| 7 | EN 1041:2008 | Information supplied by the manufacturer of medical devices |
| 8 | EN 62366:2008 | Usability Engineering Applied to Medical Devices IEC 62366:2007 |
| 9 | ISO 14644-1:2015 | Cleanrooms and associated controlled environments -- Part 1: Classification of air cleanliness by particle concentration |
| 10 | ISO 14644-2:2015 | Cleanrooms and associated controlled environments -- Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration |
| 11 | ISO 14644-3:2005 | Cleanrooms and associated controlled environments -- Part 3: Test methods |
| 12 | ISO 14644-4:2001 | Cleanrooms and associated controlled environments -- Part 4: Design, construction and start-up |
| 13 | ISO 14644-5:2004 | Cleanrooms and associated controlled environments -- Part 5: Operations |
| 14 | BS EN ISO 14644-6:2007 | Cleanrooms and associated controlled environments. Vocabulary |
| 15 | ISO 14644-7:2004 | Cleanrooms and associated controlled environments -- Part 7: Separative devices (clean air hoods, gloveboxes, isolators and mini-environments) |
| 16 | ISO 14644-8:2013 | Cleanrooms and associated controlled environments -- Part 8: Classification of air cleanliness by chemical concentration (ACC) |
| 17 | ISO 14644-9:2012 | Cleanrooms and associated controlled environments -- Part 9: Classification of surface cleanliness by particle concentration |
| 18 | ISO 14644-10:2013 | Cleanrooms and associated controlled environments -- Part 10: Classification of surface cleanliness by chemical concentration |
| 19 | EN ISO 10993-1:2009/AC:2010 | Biological evaluation of medical devices-Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2009) |
| 20 | EN ISO 10993-3:2014 | Biological evaluation of medical devices -Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity (ISO 10993-3:2014) |
| 21 | EN ISO 10993-5:2009 | Biological evaluation of medical devices-Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009) |
| 22 | EN ISO 10993-6:2009 | Biological evaluation of medical devices-Part 6: Tests for local effects after implantation (ISO 10993-6:2007) |
| 23 | ISO 10993-10:2010 | Biological evaluation of medical devices-Part 10: Tests for irritation and skin sensitization |
| 24 | EN ISO 10993-11:2009 | Biological evaluation of medical devices-Part 11: Tests for systemic toxicity (ISO 10993-11:2006) |
| 25 | EN ISO 10993-12:2012 | Biological evaluation of medical devices-Part 12: Sample preparation and reference materials (ISO 10993-12:2012) |



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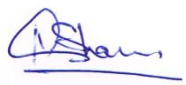
|---|---|---|
| 26 | EN ISO 10993-18:2009 | Biological evaluation of medical devices-Part 18: Chemical characterization of materials (ISO 10993-18:2005) |
| 27 | EN ISO 11137-1:2015 | Sterilization of health care products — Radiation-Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 11137-1:2006, including Amd 1:2013) |
| 28 | EN ISO 11137-2:2015 | Sterilization of health care products — Radiation -Part 2: Establishing the sterilization dose (ISO 11137-2:2013) |
| 29 | EN 556-1:2001/AC:2006 | Sterilization of medical devices — Requirements for medical devices to be designated 'STERILE'— Part 1: Requirements for terminally sterilized medical devices |
| 30 | EN ISO 11607-1:2009 | Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2006) |
| 31 | EN ISO 11607-2:2006 | Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607-2:2006) |
| 32 | EN ISO 11137-1:2015 | Sterilization of health care products-Radiation-Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 11137-1:2006, including Amd 1:2013) |
| 33 | BS EN 868-5:2009 | Packaging for terminally sterilized medical devices. Sealable pouches and reels of porous and plastic film construction. Requirements and test methods |
| 34 | ISO 5832-1:2016 | Implants for surgery -- Metallic materials -- Part 1: Wrought stainless steel |
| 35 | ISO 5832-3:2016 | Implants for surgery -- Metallic materials -- Part 3: Wrought titanium 6-aluminium 4-vanadium alloy |
| 36 | ISO 5836:1988 | Implants for surgery -- Metal bone plates -- Holes corresponding to screws with asymmetrical thread and spherical under-surface |
| 37 | ISO 9269:1988 | Implants for surgery -- Metal bone plates -- Holes and slots corresponding to screws with conical under-surface |
| 38 | ISO 9585:1990 | Implants for surgery -- Determination of bending strength and stiffness of bone plates |
| 39 | ISO 6018:1987 | Orthopaedic implants -- General requirements for marking, packaging and labelling |

Notified Body: 2460
**DNV GL NEMKO PRESAFE AS**
EC Certificate #: 247106-2017-CE-IND-NA-PS Rev. 0.0
Start of CE-Marking: 2016



Signature:
QA Manager
Date: 11/04/2019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**ANNEXURE- I**

| | |
|---|---|
| 847 | FixLOCK Proximal Humerus Plate, 3.5 mm |
| 845 | FixLOCK Plate, 3.5 mm |
| 840 | FixLOCK Proximal Tibia Plate , 4.5 mm |
| 849 | FixLOCK Broad Plate, 4.5 mm |
| 851 | FixLOCK Distal Femur Plate, 4.5 mm |
| 902 | FixLOCK Calcaneal Plate, 3.5 mm |
| 610 | DHS Barrel Plate, 4.5 mm |
| 611 | DCS Barrel Plate, 4.5 mm |


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