Document Identification Number: GPC/DoC/Implants/01/Screws

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 Screw as per Attached Annexure-01

Batch No.:
Date of Manufacturing:
Date of Expiry: NA 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.
5. Company or his authorized representative shall fulfill the obligations imposed by Annex II 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

Digitally signed by Axentii Olga
Date: 2019.04.17 08:52:33 EEST
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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 5835:1991	Implants for surgery -- Metal bone screws with hexagonal drive connection, spherical under-surface of head, asymmetrical thread – Dimensions
37	ISO 6018:1987	Orthopaedic implants -- General requirements for marking, packaging and labelling
38	ISO 9268:1988	Implants for surgery -- Metal bone screws with conical under-surface of head -- Dimensions
39	ISO 6475:1989	Implants for surgery -- Metal bone screws with asymmetrical thread and spherical under-surface -- Mechanical requirements and test methods

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

743SD	Self-Drilling, Cannulated Cancellous Screw 7.3 mm, Hexagonal Socket
760	Washer for Large Screw 13mm
765	3.5mm Locking Compression Screw Self Tapping
A704	Herbert screws dia 3.0
701	fixLOCK Self Tapping Cancellous Screw, 5.0 mm- Fully Threaded
700	fixLOCK Self-Tapping Screw, 5.0 mm
S603	DHS/DCS Lag Screw
S604	Compression Screw for DHS/DCS Lag Screw

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