



**GPC Medical Ltd.**  
Govt. of India Recognized Star Export House

*The Best Name in India  
in its field*  
Backed by experience since 1930  
**CE** ISO 9001:2008 Certified  
ISO 13485:2012 Certified  
WHO-GMP Compliant  
US FDA 510(k)

Issue No.: 01

**Document Identification Number:** GPC/DoC/Instruments/01

Revision: 04

Date: 14/10/2016

**EC DECLARATION OF CONFORMITY**



**Manufacturer:**

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



**EC Representative:**

JOMISCH  
Laan Van Keulen 58, 1827 KW Alkmaar  
The Netherlands



**Product: Orthopaedic Instruments as per Attached Annexure-01**

Batch No.:

Date of Manufacturing:

Date of Expiry:

Inv. No.

**Classification:**

Class I, Rule 1

1. We declare that our products as mentioned above, comply to the requirements to Medical Device Directive 93/42/EEC as amended by 2007/47/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 or his authorized representative shall fulfill the obligations imposed by Medical Device Directive 93/42/EEC as amended by 2007/47/EEC & ensures & declares that the Company's Products shall meet all provision of the directive as applicable.
4. 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.
5. 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**

[www.gpcmedical.com](http://www.gpcmedical.com) [www.indianorthopaedic.com](http://www.indianorthopaedic.com) [www.medical-furniture.com](http://www.medical-furniture.com) [www.anaesthesia-products.com](http://www.anaesthesia-products.com)

M Block, DDA LSC, Vikas Puri, New Delhi-110018 (India)  
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E : info@gpcmedical.com or globalproducts@bol.net.in  
CIN No. : U33119DL2004PLC130921

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### 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	<a href="#">ISO 8319-1:1996</a>	Orthopaedic instruments -- Drive connections -- Part 1: Keys for use with screws with hexagon socket heads
20	<a href="#">ISO 8319-2:1986</a>	Orthopaedic instruments -- Drive connections -- Part 2: Screwdrivers for single slot head screws, screws with cruciate slot and cross-recessed head screws

Signature:

QA Manager

Date:11/04/2019

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## ANNEXURE – I

HS1434.30	Herbert Screw Instrument Set
ILBS 716.35	Drill Sleeve for Locking Screw 3.5mm
ILBS 716.50	Drill Sleeve for Locking Screw 5.0mm
C-ILBS736.43	Drill Bit for Locking Cancellous 4.3mm Classic type
GOS 1404	DHS/DCS Plate Instrument Set with Aluminium Graphic case

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