

Technical Information/	Part: First (A)	Revision level: 02	Copy #	Page. # 01
Specification # JI/CE/PACKS/A	, ,			O

## **DECLARATION OF CONFORMITY**

We, M/s. **Jimco Industries**, **4-Km**, **Aimen Abad Road**, **Near Akbar Abad Chowk**, **Sialkot –51310-Pakistan** being manufacturer of the medical devices, ad detailed below hereby declare as required by Annex-II and Annex-VII of Medical Device Directive 93/42/EEC that our these procedure packs of medical instruments meet the applicable provisions /essential requirements of MDD Directive No. 93/42/EEC dated June 14, 1993.

We further declare that we have designated the following person as our Authorized Representative as required by article number 14 point 2 of Medical Device Directive 93/42/EEC:

Mr. Shahid Pervaiz Jimco Healthcare UK,16 Devonshire Road, Middlesbrough, TS5 6DP, London, UK.

## **Detail of the Products:**

Sterile Single Use Surgical Procedure Packs, Sterile Single Use Dental Procedure Packs and Sterile Single Use Podiatry Procedure Packs (further detail is as under):

CODE# & COMMON NAME	CLASSIFICATION	HARMONIZED STANDARDS		
DA-001-001	IIa	ISO 7153-1,	EN 980-2008	
Sterile Standard Suture Pack		ASTM F899-09,	ISO 14644-1: 1999	
DA-001-004	IIa	ASTM F 1089-10,	ISO 14644-2: 2000	
Sterile Suture Removal Pack		ISO 10993-1: 2009 EN ISO 11737-1:2006,	ISO 14644-3: 2005 ISO 14644-4: 2001	
DA-001-003	IIa	EN ISO 11737-1:2000, EN ISO 11607-1:2009,	ISO 14644-5: 2004	
Sterile Suture Procedurel Pack		EN ISO 11607-1:2009, EN ISO 11607-2:2009,	150 14044-5. 2004	
DA-007-001	IIa	EN ISO 11737-1:2009,		
Sterile Standard Delivery Pack+1		,		

**For Jimco Industries** 

**Signature** 

Name Motasim Umer Nazir

Position <u>Quality Assurance Manager</u> Place : <u>Sialkot Date</u>: <u>May 10 2016</u>