



SAO Y BẢN CHÍNH

Declaration of Conformity
10-47831-C, Rev. 03

Manufacturer: CONMED Corporation
525 French Road
Utica, New York 13502-5994 USA

EC Representative: MDSS GmbH
Schiffgraben 41
D-30175 Hannover, Germany

Classification/Rule: Class I, per Rule 6

Conformity Assessment/ Certificate: Annex VII of Directive 93/42/EEC, Annex II excluding Section 4/ CE 587783

GMDN Code/Term: 47831 Surgical Instrument Sleeve, Reusable
UMDN Code/Term: 11925 Guide Wires



GIÁM ĐỐC Nguyễn Quý Khải

Product Family: Reusable Manual Surgical Instruments

Table with 4 columns: Catalog No., Description, Technical File Number, Date 1st CE Marked. Rows include C8006, C8016, C8026, DB8TAM, SB6000, SB7000, SB8000, SB9000, SB10000, SB11000.



Runout existing supply (no new manufacturing)

Table with 4 columns: Catalog No., Description, Technical File Number, Date 1st CE Marked. Rows include DB056AM, DB056PL, 8205, 8206, DB5TAM.



**Declaration of Conformity
10-47831-C, Rev. 03**

Catalog No.	Description	Technical File Number	Date 1 st CE Marked
DB6TAM	6mm X 45 Degree Bullseye Tibial Footprint Guide	10-03	Nov, 2009
DB7TAM	7mm X 45 Degree Bullseye Tibial Footprint Guide	10-03	Nov, 2009
SB5000	5mm X 45 Degree Bullseye Femoral Footprint Guide	10-03	Nov, 2009

We, the manufacturer, hereby declare that the medical devices listed above conform to the applicable provisions of Directive 93/42/EEC, concerning medical devices.


 Kathryn Reddig
 Director, Regulatory Affairs
 CONMED Corporation

2/15/2018
 Date

DOC Change History

Date	Rev.	Description of Change	Reason for Change
22-September-2014	01	Moved catalog numbers from DOC# 10-37150-C to DOC# 10-47831-C.	Changed GMDN code for product.
02-Nov-2015	02	Added catalog no. SB9000; SB10000; SB11000. Moved catalog numbers 8205, 8206 from DOC# 10-0008 rev. AJ to this DOC.	Typo corrected. Changed GMDN code for product.
31-January-2018	03	Moved catalog no. 8205; 8206; DB5TAM; DB6TAM; DB7TAM; SB5000 to runout table.	Items moved to runout status.

