MANUFACTURER
Intra-Lock International, Inc.
6560 West Rogers Circle Bldg. #24
Boca Raton, FL 33487 – USA
Management Representative: Mary L. Jean

EC REPRESENTATIVE
Intra-Lock System Europa, S.p.A.
Via Fabrizio Pinto, 16
I-84100 Salerno – Italy

Product Name: Intra-Spin System

Classification: In accordance with MDD 93/42/EEC Annex IX

Description	Catalog No.	Class	Rule(s)
IntraSpin Centrifuge	IS220	IIa	3
Blood Collection System	BCS		
Blood Collection Tubes	BVBCTP2	IIa	2,3
Tourniquet	BTLF	1	1
Tissue Regeneration Kit	BDTRK		
Xpression Box	CTR	1	1
Surgical Tissue Forceps	BSTF	1	6
Surgical Curved Scissors	BSCS	1	6
Round Stainless Steel Bowl	BRSSMT	1	1
Rectangular Stainless Steel Bowl	BSSSMT	1	1
Dual Biomaterial Carrier Spatula	BDBC	1	6
Dual Biomaterial Packer	BDPB	1	6
Test Tube Rack	BTTRA	1	1

Notifying Body: BSI No. 0086

EC Certificate: No. CE 646982 (Expires July 17, 2022)

Initial date of CE labeling: 10/24/14

Standards Applied:

Standard Number	Standard Title
EN 556-1:2001	Sterilization of medical devices – Requirements for medical devices to be designated "STERILE" – Part 1: Requirements for terminally sterilized medical devices
EN1041:2008+A1:2013	Information Supplied by the manufacturer of medical devices
EN ISO 10993-1:2009	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process

Standards Applied (Continued):

Standard Number	Standard Title
EN ISO 11137-1:2006 + A1:2013	Sterilization of health care products – Radiation – Part 1: Requirements for development, validation and routine control of sterilization process for medical devices
EN ISO 11137- 2:2013	Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose
EN ISO 11607-1:2009	Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2:2006 +A1:2014	Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly process
EN ISO 13485:2012+AC:2012	Medical devices – Quality management system – Requirements for regulatory purposes
EN ISO 14971:2012	Medical devices – Application od risk management to medical devices
ISO 15223-1:2012	Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied
DIN EN 61010-1:2010 + Cor.: 2011	Safety requirements for electrical equipment for measurement, control, and laboratory use –Part 1: General requirements
DIN EN 61010-2-020:2007	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-020: Particular requirements for laboratory centrifuges
DIN / IEC 61326-1:2013	Electrical Equipment For Measurement, Control And Laboratory Use - Emc Requirements - Part 1: General Requirements
ISO 6710:1995	Single-use containers for venous blood specimen collection
EN14820:2004	Single-use containers for human venous blood specimen collection

Intra-Lock hereby declares that the products identified are in compliance with the provision of Annex II excluding section 4 of the European Directive 93/42 EEC of Medical Devices. The supporting documentation is retained at the premises of Intra-Lock International.

Authorized Signature: Mary L. Jean

Mary L. Jean, Management Representative
Regulatory Affairs Manager

7/12/2019
Date

Intra-Lock International, Inc.
Global Office: 6560 West Rogers Circle, Bldg. 24, Boca Raton, Florida 33487 USA ▪ Tel: (561) 447-8282 ▪ Fax: (561) 447-8283
E-mail: info@intra-lock.com ▪ Website: www.intra-lock.com