

Release date	01.03.2018	Revision	1
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MDD 93/42/EEC - 2007/47/EC DECLARATION OF CONFORMITY

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Product(s) : General Surgery Operating Tables, Gynecological-Urological
Examination and Intervention Tables- Obstetric Tables

Classification : Class I according to Medical Devices Directives Annex VII, Rule 1

We hereby declare that the products, as specified below in the attached list; the general surgery operating table, gynecological-urological examination and intervention table, obstetric tables whose models are clearly indicated below are in accordance with the requirements of the European Union MDD 93/42 / EEC amended by the Directive 2007/47 / EC Annex 2.3 starting from the date 01.03.2018.



MDD 93/42/EEC-2007/47/EC
DECLARATION OF CONFORMITY

ATTACHED LIST

DIRECTIVES CE CLASSIFICATION OF DEVICES							
EC Directives	MDD 93/42/EEC Amended by the Directive 2007/47/EC - Annex.II Article.3 – Annex.VII, Rule 1,						
Name or Identification of Medical Device and / or Accessory	Brand	Model #	GMDN Code of Product	UNSPSC Code f Product	Class	Does The Medical device Sterile	
	Types					Yes	No
General Surgery Operating Tables, Gynecological -Urological Examination and Intervention Tables- Obstetric Tables	ERM STR	200 D, 203 T, 201, 202, 203, 203 T, 204, 200 D, 2000, 2000 F	36867	42295112	I		X
	GOLDBERG	5S, 6S					
APPLIED STANDARDS		EN 60601-1, EN 60601-1-2, EN 62304, EN 60601-2-46, EN 15223-1, EN 60601-2-38, ISO 9001, ISO 13485					


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