

## EC DECLARATION OF CONFORMITY

We,

Gynetics Medical Products N.V.,  
Rembert Dodoensstraat 51  
3920 Lommel  
Belgium

Hereby declare that the CE marked products to which this declaration relates (see annex 1 for detailed product codes),

- Sterile endometrial curette (sampling);
- Sterile embryo transfer catheter;
- Sterile intra-uterine insemination catheter ;
- Sterile GIS catheter: gel instillation sonohysterography catheter.

have been classified as Class I-sterile according to Annex IX, rule number 5 and are in conformity with the essential requirements and provisions of Council Directive 93/42/EEC concerning medical devices.

These products are subject to the procedure set out in Annex VII and Annex V of the Council Directive 93/42/EEC, as amended, concerning medical devices, and are in conformity with ISO 11137-1/-2/-3, ISO 11135, ISO 10993-1/-5/-12, ISO 14644-1 and ISO 11607-1/-2.

This declaration is made on base of the quality assurance certificate number, BE19/819943674 (valid from 31 January 2020 until 30 January 2023) and BE19/819943675 (valid from 04 September 2020 until 24 May 2024) delivered by SGS Belgium NV, Notified Body 1639.

Notification number Federal Agency for Medicines and Health Products Belgium:  
Sterile endometrial curette (sampling); BE/CA01/11/1-00132-02-CLI.  
Sterile intra-uterine insemination catheter: BE/CA01/11/1-00132-04-CLI.  
Sterile embryo transfer catheter : BE/CA01/11/1-00132-05-CLI.  
Sterile GIS catheter gel instillation sonohysterography catheter: BE/CA01/1-00132-00006-CLI.

Date: 04 September 2020



Mrs M. Smeets  
Quality Manager



22/09/2020

Mrs. J. Thys  
Quality Assurance Officer

## Annex 1: Medical Devices Class I-sterile

Devices for Assisted Human Reproduction	
Product description	Sterile Embryo Transfer Catheter (Soft Embryo transfer catheter)
GMDN code	41438
Product codes	#2000 Semtrac C #2000 C TIS #2000 Semtrac Set 4.2 #2000 Semtrac Set 4.2 SP #2000 Set 4.2 TIS #2000 Set 4.2 TIS SP #2000 Semtrac Set 5 #2000 Semtrac Set 5 A #2000 Semtrac Set 5 AB #2000 Semtrac Set C5 #2000 Semtrac Set 5 SP #2000 Semtrac Set Short #2000 Semtrac Set 5 Trial #2000 Set 5 TIS #2000 Set 5 TIS SP #2000 Semtrac W-180 #2000 Semtrac W-180 SP #2000 Semtrac W-180 Trial #2000 W-180 TIS #2000 W-180 TIS SP #2000 Semtrac W-240 #2000 Semtrac W-240 SP #2000 Semtrac W-240 Trial #2000 W-240 TIS #2000 W-240 TIS SP
Product description	Sterile Embryo transfer Catheter
GMDN code	41438
Product codes	#4000 The Tulip Memo #4000 The Tulip Memo A #4000 The Tulip #4000 The Tulip A #4000 The Tulip DP #4000 Tulip S #4000 Tulip S TIS #4000 S Memo #4000 S Memo TIS #4000 Tulip L #4000 Tulip L TIS #4000 L Memo #4000 L Memo TIS #4000 Tulip LS #4000 Tulip LS TIS #4000 LS Memo #4000 LS Memo TIS #4219 Emtrac A #4219 Emtrac C-200 #4219 Emtrac C-240 #4219 Emtrac Plus #4219 Emtrac Set #4219 Emtrac Delphin #4219 Delphin TIS

Devices for Assisted Human Reproduction	
Product description	Sterile Embryo Transfer Catheter (Mandrel Embryo transfer catheter)
GMDN code	41438
Product codes	#2000 B Set 4.2 #2000 B Set 5 #2000 B W-180 #2000 B W-240 #4000 Memo B L-LS #4000 The Tulip Memo B

Devices for assisted Human Reproduction	
Product description	Sterile Intra-uterine insemination catheter/cannula
GMDN code	45846
Product codes	#4225 Smooze #4225 Smooze Medium #4225 Smooze Long #4225 Smooze Long OM #4220 IUI #4220 IUI Memo #4220 Plus

Devices for gynaecological sampling	
Product description	Sterile Endometrial curette (sampling)
GMDN code	11531
Product codes	#4164 Probet #4165 In/Out #5164 Echosampler #9164 Gynosampler-CAN #9164 Gynosampler

Sterile GIS catheter	
Product description	Gel Instillation Sonohysterography catheter
GMDN code	18746
Product codes	#5165-N970 #5165-M969 #5165-LN970 #5165-LM969