

<b>Document name:</b> Declaration of Conformity		<b>Release date:</b> 11-OCT-2022
<b>Doc ID:</b> F48		<b>Revision:</b> 008

## EU DECLARATION OF CONFORMITY

### Manufacturer information

**Manufacturer:** BIRR BioSciences BV  
 Bergseweg 4  
 3633 AK Vreeland  
 The Netherlands

**Certification:** ISO 13485:2016  
 CE 575680 BSI

### Notified Body information

**Notified Body:** BSI Netherlands  
 Say Building  
 John M. Keynesplein 9  
 1066 EP Amsterdam

**Notified Body Number:** CE2797

### Product information

Product Name (as per product label)	Classification	Rule	GMDN Codes
1710-2 Follicle Puncture Set 17G 35 cm	Class IIa	Annex IX, Rule 6	45433
1712 Follicle Puncture Needle 17G flush	Class IIa		
1714-2 Follicle Puncture Set	Class IIa		
1718-2 Follicle Puncture Set 17G	Class IIa		
1720-2 Follicle Puncture Set 17G	Class IIa		
17100100SLO Follicle Puncture Needle 17G	Class IIa		
18100100SLO Follicle Puncture Needle 18G	Class IIa		
113501 Conical Tube 15 ml PP x 10	Class IIa	Annex IX, Rule 2	56660
113506 Conical Tube 15 ml PS x 10	Class IIa		
113510 Conical Tube 50 ml PP	Class IIa		
113511 Conical tube PP 11 ml x 10	Class IIa		
113515 Round Bottom Tube 5 ml	Class IIa		
113516 Round Bottom Tube 5 ml x 10	Class IIa		
113520 Round Bottom Tube 14 ml	Class IIa		
113521 Round Bottom Tube 14 ml x 10	Class IIa		
113601 Flask 40 ml x 5	Class IIa		
113650 Flask 270 ml	Class IIa		
113301 Microvial 1.5 ml x 10	Class IIa		
113101 Semen collection container 125 ml with LOT label	Class IIa		
113102 Semen collection container 100 mL	Class IIa		38522
113701 Serological Pipette 1 ml	Class IIa		
113702 Serological Pipette 2 ml	Class IIa		
113705 Serological Pipette 5 ml	Class IIa		
113710 Serological Pipette 10 ml	Class IIa		

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113725 Serological Pipette 25 ml	Class IIa				
113410 Dropping Pipette 1 ml	Class IIa				
113411 Dropping Pipette 1 ml x 10	Class IIa				
113420 Dropping Pipette 3 ml	Class IIa				
113421 Dropping Pipette 3 ml x 10	Class IIa				
113060 Petri Dish 60 mm	Class IIa				
113061 Petri Dish 60 mm x 4	Class IIa				
113090 Petri Dish 90 mm	Class IIa				
113098 Petri Dish 90 mm x 8	Class IIa				
1130056, 5-Well Dish x 6	Class IIa				
113006 6-Well Dish x 6	Class IIa				
113016 16-Well Dish x 6	Class IIa				
11304+8 4 + 8 Well Dish x 10	Class IIa				
113030TL Culture Dish 35 mm Time Lapse	Class IIa				
113031TL Culture Dish 35 mm Time Lapse x 10	Class IIa				
1130-ICSI ICSI Dish 60 mm	Class IIa				
1131-ICSI ICSI Dish 60 mm x 10	Class IIa				
1130116, Square ICSI Dish x 6	Class IIa				
1130-CW; Centre Well Dish 60 mm	Class IIa				
1131-CW Centre Well Dish 60 mm x 10	Class IIa				
1130106, Square Center Well Dish x 6	Class IIa				
113030 Culture Dish 35mm	Class IIa				
113031 Culture Dish 35 mm x10	Class IIa				
1681A Ovum Pick up Pipette 9 cm LL	Class IIa				
1682A Ovum Pick up Pipette 3 cm LL	Class IIa				
1670 Inspection Pipette	Class IIa				
1671 Embryo Handling Pipette	Class IIa				
1673 Insemination Pipette	Class IIa				
1685 Pasteur Pipette 15 cm, x 6	Class IIa				
1686 Pasteur Pipette 23 cm x 6	Class IIa				
15240 FBS Scalpel	Class IIa			Annex IX, Rule 6	16783
15271 FBS Set	Class IIa				
15250 FBS Capillary	Class IIa				

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Directive information

Applicable Directive: European Communities Council Directive 93/42/EEC  
Concerning Medical Devices  
(including the revision from the Directive 2007/47/EC.)  
Medical Device Assessment: Conform MDD article 11 and Annex V

Management Declaration

*On behalf of BIRR Biosciences, the undersigned declares that the product(s) described in this document meet the provisions of the Essential Requirements in Annex 1 of the Council Directive 93/42/EEC, as last amended by 2007/47/EC*

This declaration covers all products manufactured from of 11 October 2022 and onwards till a reissued DoC has been released

Signed by the Company authorized representative:



Loïc Brandsma, QA/RA Manager

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