

<b>Document name:</b> Declaration of Conformity – ART Container	<b>Record ID:</b>	TD10-7.Z-1
	<b>Revision:</b>	1.0

## EU DECLARATION OF CONFORMITY

### MANUFACTURER INFORMATION

**NAME:** BIRR BioSciences BV  
**ADDRESS:** Bergseweg 4  
 3633 AK Vreeland  
 The Netherlands  
**CERTIFICATION:** ISO 13485:2016 and EN ISO 13485:2016  
 CE BE25/00000073 SGS  
**SRN:** NL-MF-000023194

### NOTIFIED BODY INFORMATION

**NOTIFIED BODY:** SGS Belgium NV  
**NOTIFIED BODY NAME:** SGS Belgium NV  
**NOTIFIED BODY ADDRESS:** Noorderlaan 87, BE-2030 Antwerpen  
**NOTIFIED BODY NUMBER:** NB 1639

### DEVICE INFORMATION

<b>TD Number – Name:</b>	TD10 - ART Container
<b>Intended use:</b>	ART Container is intended for collecting and processing gametes for use in assisted reproduction technologies.
<b>Basic UDI-DI:</b>	87179737110YM
<b>Class, Rule:</b>	Class IIa, According Annex VIII Rule 2
<b>EMDN:</b>	U080207 Containers for preparation of biological material for assisted reproduction.

### PRODUCT INFORMATION

Product Code	Product Name	Units/ Pack	GMDN Codes/
113102	Semen Collection Container 100 mL	5 (individually sealed)	63772
113103	Semen Collection Container 100 mL	1	
113303	Microvial PP	10	56660
113506	Conical Tube PS 15 mL	10	
113511	Conical Tube PP 11 mL	10	
113550	Conical Tube PP 50 mL	1	
113515	Round Bottom Tube 5 mL	1	
113516	Round Bottom Tube 5 mL	10	
113520	Round Bottom Tube 14 mL	1	
113521	Round Bottom Tube 14 mL	10	

### APPLICABLE REGULATION INFORMATION

**Applicable Regulation:** European Medical Device Regulation (EU) 2017/745  
  
**Medical Device Conformity Assessment:** Conform MDR 2017/745 Article 52; and Annex IX

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Common Specification: N.A

**Statement**

*This EU declaration of conformity is issued under the sole responsibility of the manufacturer  
 The devices that are covered by the present declaration are in conformity with MDR (EU) 2017/745.*

**Management Declaration**

*On behalf of BIRR Biosciences, the undersigned declares that the product(s) described in this document meet the provisions of the EU Medical Device Regulation 2017/745 (MDR (EU) 2017/745).*

This declaration covers all products manufactured from 2025-03-21 and onwards till a reissued DoC will be released. Beside this following single batches of products are covered by this DoC

Product	Description article	Lotnummer
113103	Semen container 100ml	25065
113506	Conical Tube PS 15ml. per 10	25030
113550	Conical Tube PP 50ml. single packed	24011
113511	Conical Tube PP 11 ml. per 10	24988
113511	Conical Tube PP 11 ml. per 10	25067
113515	Round Bottom Tube 5mL single packed	24003
113516	Round Bottom Tube 5ml. per 10	25031
113516	Round Bottom Tube 5ml. per 10	25057
113520	Round Bottom Tube 14ml. single pack	24004
113521	Round Bottom Tube 14mL. per 10	25024
113521	Round Bottom Tube 14mL. per 10	25046
113303	Micro vial PP per 10	24010

Signed by the Company authorized representative:

Name: Tom Vermeiden  
 Function: CEO  
 Place: Vreeland  
 Date: 2025-03-21  
 Signature: 