

<b>Document name:</b> Declaration of Conformity – ART Pipettes	<b>Record ID:</b>	TD20-7.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>	TD20 - ART Pipettes
<b>Intended use:</b>	The ART Pipettes are medical devices to be used for handling of gamete, embryos, culture media and oil for use in assisted reproduction technologies
<b>Basic UDI-DI:</b>	87179737120YQ
<b>Class, Rule:</b>	Class IIa, According Annex VIII Rule 2
<b>EMDN:</b>	U0802030199: Pipettes for assisted reproduction - other.

### PRODUCT INFORMATION

Product Code	Product Name	Units/ Pack	GMDN Codes/
113410	Dropping Pipette 1 mL	1	46553
113411	Dropping Pipette 1 mL	10	
113420	Dropping Pipette 3 mL	1	
113421	Dropping Pipette 3 mL	10	
113701	Serological Pipette 1 mL	1	
113702	Serological Pipette 2 mL	1	
113705	Serological Pipette 5 mL	1	
113710	Serological Pipette 10 mL	1	
113725	Serological Pipette 25 mL	1	

### 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  
Common Specification: N.A

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### **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 1
113420	Dropping pipette 3ml. single packed	25062
113421	Dropping pipette 3ml. per 10	25063
113701	Serological Pipette 1 ml	3116E-BB
113702	Serological Pipette 2 ml	3188E-BB
113705	Serological Pipette 5 ml	3044E-BB
113710	Serological Pipette 10 ml	3030E-BB
113725	Serological Pipette 25 ml	3244K-BB

Signed by the Company authorized representative:

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

Signature:

