

Document name: Declaration of Conformity – ART Dish	Record ID:	TD03-7.Z-1
	Revision:	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

NOTIFY BODY INFORMATION

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

DEVICE INFORMATION

TD Number – Name:	TD03 - ART Dish
Intended use:	ART Dish is intended for preparing and culturing gametes or embryos for use in assisted reproduction techniques (ART).
Basic UDI-DI:	87179737103YQ
Class, Rule:	Class IIa, According Annex VIII Rule 2
EMDN:	U080206 Culture plates for assisted reproduction

PRODUCT INFORMATION

Product Code	Product Name	Units/ Pack	GMDN Codes/
1130056	5-Well Dish	6	56648
113006	6-Well Dish	6	
113016	16-Well Dish	6	
1134+8	4+8 Well Dish	10	
113030TL	Culture Dish 35 mm Time Lapse	1	
113031TL	Culture Dish 35 mm Time Lapse	10	
113030	Culture Dish 35 mm	1	
113031	Culture Dish 35 mm	10	
113060	Culture Dish 60 mm	1	
113061	Culture Dish 60 mm	10	
113090	Culture Dish 90 mm	1	
113098	Culture Dish 90 mm	8	
1130-CW	Center Well Dish	1	
1131-CW	Center Well Dish	10	
1130106	Center Well Dish	6	
1130-ICSI	ICSI Dish	1	
1131-ICSI	ICSI Dish	10	
1130116	ICSI Dish	6	

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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

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	Lotnumber
1130-CW	Center Well Dish 11 x 60 mm, single	25029
1130-ICSI	ICSI Dish 9 x 60 mm, single packed	24015
1130056	5-Well Dish with round edges per 6	25021
1130056	5-Well Dish with round edges per 6	25040
113006	6-Well dishes per 6	24002
1130116	Square ICSI dish per 6	25042
113030	Culture Dish 11x35 mm single packed	24014
113016	16-Well dishes per 6	25045
113030TL	Culture Dish 35 mm Time Lapse singl	24013
113031	Culture Dish 11 x 35 mm, per 10	25037
113031TL	Culture Dish 35mm Time Lapse per 10	25036
113060	Culture Dish 15x60 mm single packed	24016
113060	Culture Dish 15x60 mm single packed	25056
113061	Culture Dish 15 x 60 mm, per 10	24005
113061	Culture Dish 15 x 60 mm, per 10	25068
113090	Culture Dish 15x90 mm single packed	25025
113090	Culture Dish 15x90 mm single packed	25050
113098	Culture Dish 15 x 90 mm per 8	24012
113098	Culture Dish 15 x 90 mm per 8	25047
1131-CW	Center Well Dish 11 x 60 mm, per 10	25019
1131-ICSI	ICSI Dish 9 x 60 mm, per 10	24992
1134+8	4+8 Well Dish , per 10	24018
1134+8	4+8 Well Dish , per 10	25069



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Signed by the Company authorized representative:

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