Declaration of Conformity

To Council Directive 93/42/EEC of 14 June 1993 Concerning Medical Devices

Manufacturer:	**miraDry, Inc.** 2790 Walsh Avenue Santa Clara, CA 95051 USA
European Representative:	**Psephos Limited** GMIT iHub Galway Dublin Road Galway H91 DCH9 Ireland
Medical Devices:	**Product Name: miraDry System** **GMDN No.: 11490**

Model/Catalogue Number	*Description*
MD4000-MC-XX[1]	miraDry Console
MD4000-HP-XX[2]	miraDry Handpiece
MD4500-BT	miraDry bioTip

Classification – Annex IX:	Class IIb, Rule 9
Conformity Assessment Route:	Annex II

We, the manufacturer, herewith declare that the stated Medical Devices meet the Transposition into National Law, the provisions of council Directive 93/42/EEC of 14 June 1993 concerning Medical Devices – as amended by Directive 2007/47/EC. All supporting documentation are retained at the premises of the manufacturer.

Notified Body:	**NSAI** 1 Swift Square Northwood Santry, Dublin 9 Ireland
Identification Number:	0050
(EC) Certificate:	252.907
Start of CE-Marking:	December 20, 2013
Place, Date of Declaration:	Monument(CO, USA), February 2, 2022
Signature:	Irene Mo Irene Mo Vice President of Regulatory, Quality & Clinical

[1] *Where models differ for different countries (e.g. require a different power cord or user's manual), the model number may have a –XX suffix, where XX represents the country or region.*
[2] *Refer to footnote 1.*

miraDry, Inc.	*Document Title*	*Document Number*	*Revision*	*CO #*	*Date Effective*
	Declaration of Conformity, miraDry System	**DH0208**	B	**22-0012**	**02/02/2022**

Declaration of Conformity

Manufacturer:		**miraDry, Inc.** 2790 Walsh Avenue Santa Clara, CA 95051 USA	
European Representative:		**Psephos Limited** GMIT iHub Galway Dublin Road Galway H91 DCH9 Ireland	
Medical Devices:		**Product Name: miraDry Accessories**	
	GMDN No.: 11490	***Model/Catalogue Number***	***Description***
		MD4000-TS2	miraDry template system
		MD4000-TS2-50	miraDry template refills
		MD4000-TS2-60	
		MD4000-TS2-70	
		MD4000-TS2-80	
		MD4000-TS2-TU	
		MD4000-TS2-SIZING	
		MD4000-PK	miraDry Primer Kit
	GMDN No.: 15593	***Model/Catalogue Number***	***Description***
		MD4000-AR	miraDry Armrest
	GMDN No.: 34964	***Model/Catalogue Number***	***Description***
		MD4000-IP	miraDry Ice Packs
Technical File Numbers:		**DH0110 and DH0111**	
Classification – Annex IX:		**Class I, Rule 1**	
Conformity Assessment Route:		**Annex VII**	

We, the manufacturer, herewith declare that the stated Medical Devices comply with the Essential Requirements of the Council Directive 93/42/EEC of 14 June 1993 concerning Medical Devices – as amended by Directive 2007/47/EC. All supporting documentation are retained at the premises of the manufacturer.

Start of CE-Marking: December 31, 2013

Place, Date of Declaration: Monument(CO, USA), February 2, 2022

Signature:

Irene Mo

Irene Mo
Vice President of Regulatory, Quality, and Clinical

miraDry, Inc.	*Document Title*	*Document Number*	*Revision*	*CO #*	*Date Effective*
	Declaration of Conformity, miraDry Accessories	**DH0209**	B	**22-0012**	**02/02/2022**