EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 585708**

Issued To: **Mirage Health Group Ltd**
Unit 11 Tewin Court
Welwyn Garden City
AL7 1AU
United Kingdom

In respect of:

The design and manufacture of ear irrigators and consumables.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2012-11-13** Date: **2021-03-18** Expiry Date: **2022-11-12**

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Supplementary Information to CE 585708

Issued To:

Mirage Health Group Ltd
Unit 11 Tewin Court
Welwyn Garden City
AL7 1AU
United Kingdom

NBOG code(s)	Device Description	Intended purpose
Class IIa		
MD 1101	Propulse	N/A for class IIa devices

First Issued: **2012-11-13** Date: **2021-03-18** Expiry Date: **2022-11-12**

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By Royal Charter

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 585708**
Date:	**2021-03-18**
Issued To:	**Mirage Health Group Ltd** **Unit 11 Tewin Court** **Welwyn Garden City** **AL7 1AU** **United Kingdom**

Subcontractor:	**Service(s) supplied**
Medical Device Management Ltd Block B, The Crescent Building Northwood Santry Dublin 9 D09 C6X8 Ireland	**EU Representative**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 585708**
Date: **2021-03-18**
Issued To: **Mirage Health Group Ltd**
Unit 11 Tewin Court
Welwyn Garden City
AL7 1AU
United Kingdom

Date	Reference Number	Action
13 November 2012	7818423	First issue
10 May 2017	8282533	Reissue due to change of company address to 1 Little Mundells, Welwyn Garden City Hertfordshire AL7 1EW Removal of 'Gimelli Laboratories' as a significant subcontractor for 'design and manufacture'.
01 November 2017	8760923	Renewal of CE 585708 certificate
30 July 2019	8728710	Traceable to NB 0086.
Current	3368110	Change of company address to "Unit 11 Tewin Court, Welwyn Garden City, AL7 1AU, United Kingdom". Removal of Dental Irrigators from scope of certificate. Product table added. Inclusion of "Medical Device Management Ltd, Block B, The Crescent Building, Northwood, Santry, Dublin 9, D09 C6X8, Ireland" as EU authorized representative.