



By Royal Charter

# EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

**MDR 818931 R000****Manufacturer:** Mirage Health Group Ltd**Address:**

Unit 11 Tewin Court  
Welwyn Garden City  
AL7 1AU  
United Kingdom

**Single Registration Number:** GB-MF-000007803**EU Authorised Representative:** Medical Device Management Ltd**Address:**

Block B, The Crescent Building  
D09 C6X8, Dublin 9  
Ireland

**Scope:** See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II certificate is required.

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

Graeme Tunbridge, Senior Vice President Global Regulatory &amp; Quality

First Issue Date: **2025-11-19**Starting Validity Date: **2025-11-19**Current Issue Date: **2025-11-19**Expiry Date: **2030-11-18**...making excellence a habit.<sup>TM</sup>

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.  
This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80  
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at Seventh and Eighth Floors, The Acre, 90 Long Acre, London, WC2E 9RA, UK.  
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## Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Ear Irrigator and Consumables	Class IIa



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## Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
Current	30294355	Issued

**First Issue Date: 2025-11-19****Starting Validity Date: 2025-11-19****Current Issue Date: 2025-11-19****Expiry Date: 2030-11-18***...making excellence a habit.™*

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