By Royal Charter

EU Quality Management System Certificate

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

MDR 732087 R000

Manufacturer: Johnson & Johnson Vision Care, Inc.

Address:
7500 Centurion Parkway
Jacksonville
Florida
32256
USA

Single Registration Number: Not Available

EU Authorised Representative: AMO Ireland

Address:
Block B
Liffey Valley Office Campus
Quarryvale
Co. Dublin
D22 X0Y3
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 and Class IIb implantable devices an 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 Medical Devices

First Issue Date: **2021-10-26**

Current Issue Date: **2023-01-26**

Starting Validity Date: **2023-01-26**

Expiry Date: **2026-10-25**

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Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Daily disposable silicone hydrogel contact lenses for refractive vision correction	Class IIa
Daily wear and extended wear silicone hydrogel contact lenses for refractive vision correction and bandage indication.	Class IIa
Daily wear (including daily disposable and reusable wear) and extended wear hydrogel contact lenses for refractive vision correction	Class IIa
Daily wear (including daily disposable and reusable wear) silicone hydrogel contact lenses for refractive vision correction and attenuation of bright light.	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
2021-10-26	3254121	Issued
2022-09-16	3731375	Supplemented – Addition of hydrogel devices
Current	3847518	Supplemented – Addition of light attenuation devices

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