

# EU Quality Management System Certificate

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

## MDR 769862 R000

**Manufacturer:** PSI/EYE-KO, Inc.

**Address:**

804 Corporate Centre Drive  
O'Fallon  
Missouri  
63368  
USA

**Single Registration Number:** US-MF-000022109

**EU Authorised Representative:** Advena Ltd

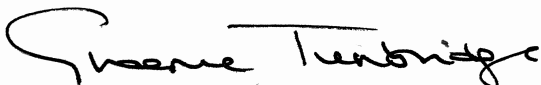
**Address:**

Tower Business Centre  
2nd Flr.  
Tower Street  
Swatar, BKR 4013  
Malta

**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 Medical Devices

First Issue Date: **2023-03-24**

Current Issue Date: **2023-03-24**

Starting Validity Date: **2023-03-24**

Expiry Date: **2028-03-23**

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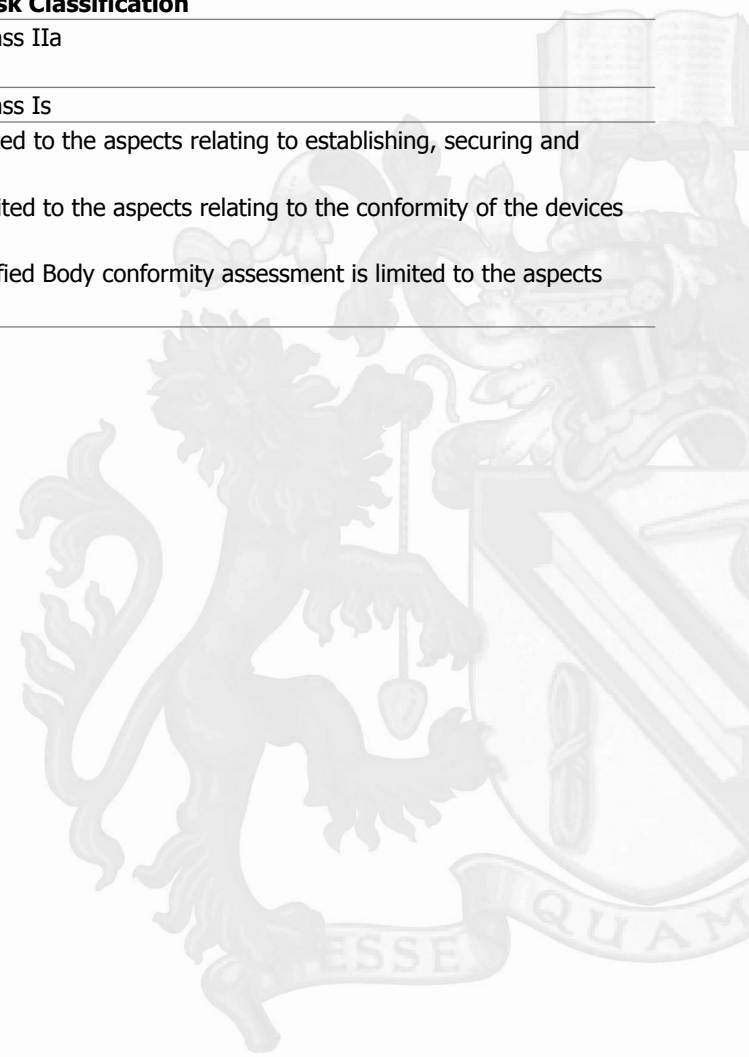
### Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Single use cannulas, needles, cystotomes and disposable handheld surgical instruments for ophthalmology	Class IIa
Single use ophthalmic speculum	Class Is

For Class Is devices, the Notified Body conformity assessment is limited to the aspects relating to establishing, securing and maintaining sterile conditions.

For Class Im devices, the Notified Body conformity assessment is limited to the aspects relating to the conformity of the devices with the metrological requirements.

For Class Ir devices (Class I re-usable surgical instruments), the Notified Body conformity assessment is limited to the aspects relating to the reuse of the device.



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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	3663480	Issued



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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.