Declaration of Conformity

Manufacturer Address:	New World Medical, Inc. 10763 Edison Court Rancho Cucamonga, CA 91730 USA Phone: +1(909)466-4304 Website: www.newworldmedical.com
European Representative:	Emergo Europe Prinsessegracht 20 2514 AP The Hague The Netherlands Tel: (31) (0) 70 345-8570 Fax: (31) (0) 70 346-7299 Email: EmergoVigilance@ul.com
Notified Body:	GMED Groupe LNE (0459) EC Certificate: Certificate No. 31829 Rev. 7 Effective Date: March 11th, 2021 Expiry Date: May 26th. 2024 GMED Address: 1 rue Gaston Boissier 75015 Paris France
Product:	AHMED® Glaucoma Valve (Glaucoma Shunts)
GMDN Code:	**42526** - A sterile device designed to regulate the flow of fluid between the anterior chamber and the space around the conjunctiva of the eye by allowing flow when the pressure in the chamber is above a pre-set value (e.g., 8 to 10 mmHg). It is typically a very small (e.g., slit) valve implanted in the eye as a component of an eye stent, and typically used in patients with advanced glaucoma when, despite the use of medication, laser treatments, or a previous glaucoma filtration procedure (trabeculectomy), the addition of a drainage tube and valve (aqueous shunt) is recommended.

Conformity Assessment: Annex II (excluding Section 4) of Directive 93/42/EEC

Classification (MDD, Annex 9): IIb per Rule 8

Regulation Compliance Statement:

New World Medical declares that the AHMED® Glaucoma Valve models meet the provision of the Council Directive 93/42/EEC for Medical Devices and Directive 93/42/EEC as transposed into the national laws of the Member States.

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Applicable Standards: Refer to Section 8

Where Applicable Additional Information:

New World Medical hereby declares the following for AHMED® Glaucoma Valve

- AHMED® Glaucoma Valve is not an electrical device or an electrical equipment and hence the regulations for RoHS do not apply.
- AHMED® Glaucoma Valve models do not contain Substances of Very High Concern (SVHC) as listed by the European Chemicals Agency (ECHA) under the provisions of Regulation (EC) No. 1907/2006 of the European Parliament and of the council concerning the Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH) per the ECHA 20/12/2010 and previous updates and to the best of our knowledge our products do not contain these substances.
- AHMED® Glaucoma Valve models are single use, i.e., single-patient, single procedure and single purpose use. The device should not be reprocessed, re- sterilized, and re-used.
- AHMED® Glaucoma Valve models do not incorporate, as an integral part, a medicinal product.
- AHMED® Glaucoma Valve models are latex-free and does not contain phthalates. This statement comprises the medical device, its packaging as well as its manufacturing processes
- AHMED® Glaucoma Valve models does not contain software
- AHMED® Glaucoma Valve models does not contain tissue of biological origin, i.e., does not contain tissue of animal origin or (human) blood derivatives
- AHMED® Glaucoma Valve models sterility, safety and performance are guaranteed for a period of 24 months after sterilization.
- AHMED® Glaucoma Valve models are sterilized using Gamma Irradiation sterilization process.

[redacted]

California, USA June 22, 2021

Place and date of Issue

Cristina Avalos, Director QA/RA

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Addendum to the Declaration of Conformity

This addendum to the Declaration of Conformity of the AHMED® Glaucoma Valve (Glaucoma Shunts) for **New World Medical** is effective as of the date last executed below and is subject to all other terms of the existing declaration.

By this addendum, the European Representative's (**Emergo Europe B.V.**) address is changed to the below:

Westervoortsedijk 60
6827 AT Arnhem
The Netherlands

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California, USA August 28, 2023
Place and date of Issue

Cristina Avalos, VP of QA/RA

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