PERFLUORON (purified perfluoro-n-octane liquid) FID 98156, FW-SG-036

STATEMENT OF COMPATIBILITY
(Article 22, EU MDR 2017/745)

Technical Documentation Identification: FW-SG-036

Supersedes (Date): First Issue

Assembler:

Alcon Laboratories, Incorporated

Assembler Address:

6201 South Freeway, Fort Worth, TX 76134-2099, USA

Procedure Pack or System	GMDN Code & Term	Global Codes/SKUs
Surgical PERFLUORON Kit	36108 Aqueous/ vitreous humour replacement medium kit	Surgical PERFLUORON Kit with 5 mL vial: 8065900111 0090010018 Surgical PERFLUORON Kit with 7 mL vial: 8065900112 0090010019

This Statement is applicable to all Procedure Packs and Systems listed and manufactured after the Date of Issuance of this Manufacture Statement and until a new Statement is issued.

We hereby declare that:

a) **We have verified the mutual compatibility of the devices in accordance with the manufacturer(s) instructions and carried out our operations in accordance with these instructions.**
b) **We have packaged the procedure pack or system and supplied relevant information to users incorporating relevant instructions from the manufacturer(s).**
c) **The whole activity was subject to appropriate methods of internal control or inspection.**

☐ **If checked then, the procedure pack or system has been sterilized by the assembler and the following information is applicable:**

- **The sterilization of this procedure pack or system has been carried out in accordance with the manufacturer(s) instructions for the devices contained within.**
- **The following Notified Body has been involved in the conformity assessment of the aspects related to sterilization of the procedure pack or system in accordance with the Conformity Assessment Route identified below:**

Annex IX ☐ **or** Annex XI ☐

Notified Body: N/A

Identification number: N/A

PERFLUORON (purified perfluoro-n-octane liquid) FID 98156, FW-SG-036

Notified Body Address: N/A

Notified Body Identification No.: N/A

Notified Body Certificate No: N/A

Signature: Lemke, Sylvia Digitally signed by Lemke, Sylvia DN: cn=Lemke, Sylvia, ou=PDF Internal Signing, o=Alcon Vision, LLC Reason: I am approving this document Date: 2021.05.26 11:36:47 -07'00' Adobe Acrobat DC version: 2015.006.30503 Date:_____

Name: Sylvia Lemke

Title/Function: Senior Director, Global Regulatory Affairs

For and on behalf of Alcon Laboratories Inc.

4.2 Harmonized Standards and Common Specifications

PERFLUORON FID 98156

Alcon acknowledges that the General Safety and Performance Requirements are fulfilled through compliance with quality system requirements, standards, regulations, and guidance documents. Non-product specific guidance and other regulatory documents (e.g. MEDDEV, WHO guideline) are acknowledged as part of the General Safety and Performance Requirements and are referenced in relevant Standard Operating Procedures (SOP) within Alcon's Quality Management System. As such, Alcon's Quality Management System is maintained and audited for compliance with ISO / EN ISO 13485. Product specific standards are identified below in the List of Applicable Standards.

Alcon ensures product compliance via the Reference Standards Management Process

Document Number	Title
ASTM F2475:2020	Standard Guide For Biocompatibility Evaluation Of Medical Device Packaging Materials
EN 1041:2008+A1:2013	Information supplied by the manufacturer of medical devices
EN 285:2015	Sterilization — Steam sterilizers — Large sterilizers
EN 556-1:2001	Sterilization of medical devices - Requirements for medical devices to be designated 'STERILE' – Part 1: Requirements for terminally sterilized medical devices
EN 556-2:2015	Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" – Part 2: Requirements for aseptically processed medical devices
EN 62366-1:2015+A1:2020	Medical devices – Part 1: Application of usability engineering to medical devices
EN ISO 10993-1:2020	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process – Technical Corrigendum 1
EN ISO 10993-10:2013	Biological evaluation of medical devices Tests for irritation and skin sensitization
EN ISO 10993-12:2012	Biological evaluation of medical devices – Part 12: Sample preparation and reference materials
EN ISO 10993-5:2009	Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity
EN ISO 10993-6:2016	Biological evaluation of medical devices -- Part 6: Tests for local effects after implantation

EN ISO 11138-3:2017	Sterilization of health care products -- Biological indicators - Part 3: Biological indicators for moist heat sterilization processes
EN ISO 11140-1:2014	Sterilization of health care products – Chemical indicators – Part 1: General requirements
EN ISO 11607-1:2020	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2:2020	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
EN ISO 11737-1:2018	Sterilization of Medical Devices – Microbiological Methods – Part 1:Determination Of A Population Of Microorganisms On Products TECHNICAL CORRIGENDUM 1
EN ISO 13408-1:2015	Aseptic processing of health care products -- Part 1: General requirements
EN ISO 13408-2:2018	Aseptic processing of health care products -- Part 2: Sterilizing filtration
EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes – Technical Corrigendum 1
EN ISO 14155:2020	Clinical investigation of medical devices for human subjects – Good clinical practice - Technical Corrigendum 1
EN ISO 14644-1:2015	Cleanrooms and associated controlled environments Part 1: Classification of air cleanliness by particle concentration
EN ISO 14644-2:2015	Cleanrooms and associated controlled environments -- Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration
EN ISO 14971:2019	Medical devices – Application of risk management to medical devices
EN ISO 15223-1:2016	Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements
EN ISO 16672:2020	Ophthalmic implants - Ocular endotamponades
EN ISO 17665-1:2006	Sterilization of health care products -- Moist heat -- Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices
EN ISO 22442-1:2020	Medical devices utilizing animal tissues and their derivatives – Part 1: Application of risk management
EN ISO 22442-2:2020	Medical devices utilizing animal tissues and their derivatives – Part 2: Controls on sourcing,

	collection and handling
EN ISO 22442-3:2007	Medical devices utilizing animal tissues and their derivatives – Part 3: Validation of the elimination and/or inactivation of viruses and transmissible spongiform encephalopathy (TSE) agents
ICH Q1A(R2):2003	Note For Guidance on Stability Testing: Stability Testing of New Drug Substances And Products
ICH Q2(R1):2005	Validation of Analytical Procedures: Text and Methodology
ISO 3166-1:2020	Codes for the representation of names of countries and their subdivisions – Part I: Country Codes
ISO 639-1:2002 (R2019)	Codes for the Representation of Names of Languages - Part 1: Alpha-2 Code
ISO 7000:2019	Graphical Symbols for Use on Equipment - Registered Symbols
ISO/TR 15499:2016	Biological evaluation of medical devices - Guidance on the conduct of biological evaluation within a risk management process
ISTA 2A:2011	Packaged-Products Weighting Over 150 Pounds (68kg)
European Pharmacopoeia <2.6.1>	Sterility
European Pharmacopoeia <2.6.12>	Microbiological Examination of Non-Sterile Products: Microbial Enumeration Tests
European Pharmacopoeia <2.6.14>	Bacterial Endotoxins
European Pharmacopoeia <3.2.9>	Rubber Closures for Containers for Aqueous Parenteral Preparations, for Powders and for Freeze Dried Powders
United States Pharmacopeia <467>	Residual Solvents
United States Pharmacopeia <61>	Microbiological Examination of Nonsterile Products: Microbial Enumeration Tests
United States Pharmacopeia <661>	Containers-Physicochemical Tests-Plastics
United States Pharmacopeia <71>	Sterility
United States Pharmacopeia <789>	Particulate Matter
United States Pharmacopeia <85>	Bacterial Endotoxins Test