



MANUFACTURER'S DECLARATION OF CONFORMITY

FULL QUALITY ASSURANCE PROCEDURES

This is a declaration of conformity made in accordance with the requirements of Annex II, excluding section 4, of the European Medical Device Directive 93/42/EC relating to the devices stated in the attached schedule.

Reference: DoC 0001 - Disposable Ophthalmic Instruments, revision 13

Manufacturer's name: Vitreo B.V.

Business address: Seggelant-Noord 2
3237 MG Vierpolders
The Netherlands

Medical device(s): see attached schedule for multiple products

Classification: see attached schedule for the class of multiple products

GMDN code and term:

62478	Ophthalmic soft-tissue surgical forceps, probe-like, single-use
63478	Intraocular scissors, probe-like, single-use
58070	Vitrectomy contact lens, single-use
47130	Vitrectomy fluid/gas handling instrument
46705	Ophthalmic infusion/aspiration cannula, single-use

Scope of application: All

Each kind of medical device to which the system has been applied complies with the applicable provisions of the essential principles, the classification rules, and the full quality assurance procedures, at each stage, from the design of the device until its final inspection before being supplied.

Notified Body involved in the conformity assessment procedure: DQS Medizinprodukte GmbH
August-Schanz-Straße 21
60433 Frankfurt am Main
Germany



Quality Management certificate: DQS-MED EN ISO 13485 Certificate number 527668 MP2016

CE certificate: DQS-MED CE Certificate number 527668 MR2

Standards applied: EN 556-1:2001-AC:2006 / EN 1041:2008 -A1:2013 /
EN ISO 10993-1:2009-AC:2010 / EN ISO 10993-5: 2009 / EN ISO 10993-10:
2013 / EN ISO 10993-7:2008-AC:2009 /
EN ISO 11135: 2014+A1:2019 / EN ISO 11607-1:2020 /
EN ISO 11607-2:2020/ EN ISO 13485:2016 / EN ISO 14971:2012 / EN ISO
15223-1:2016 / EN IEC 62366:2015 +C1:2016

Standards applied (product specific): ISO 7153-1:2016 / EN-ISO 5832-6:2019 / EN ISO 6009:2016

This declaration is issued under the sole responsibility of the manufacturer.

The declaration of conformity has a validity period limited by the issue of a revised declaration of conformity and/or by the expiration date of the certificates issued by the notified body, which is 28-03-2022.

Schedule for multiple products

Authorised signatory:

Alwin van der Elburg, COO

Name, Position

16JUN2021

Date

Vitreco B.V.
Seggelant-Noord 2
3237 MG Vierpolders
The Netherlands

This schedule for multiple products is an attachment to the Declaration of Conformity identified in the heading.
The following table identifies the products included in the product family with the corresponding GMDN code and term.
The products are identified with the ordering number, product description, device identification number, introduction date and classification according to Annex IX of the Council Directive 93/42/EEC concerning medical devices.

GMDN 62478	Ophthalmic soft-tissue surgical forceps, probe-like, single-use				
	FC23.D02	23G Forceps, Serrated Gripping	8719214220099	18-02-2016	Class IIa
	FC23.D03	23G Forceps, ILM Endgripping	8719214220112	18-02-2016	Class IIa
	FC23.D04	23G Forceps, Asymmetrical Endgripping	8719214220136	18-02-2016	Class IIa
	FC23.D05	23G Forceps, Eckardt Endgripping	8719214220150	18-02-2016	Class IIa
	FC23.D06	23G Forceps, Kuhn 45° Power Gripping	8719214221881	27-06-2016	Class IIa
	FC23.D07	23G Forceps, Shah Xtra Grip	8719214221935	09-11-2016	Class IIa
	FC25.D02	25G Forceps, Serrated Gripping	8719214220174	18-02-2016	Class IIa
	FC25.D03	25G Forceps, ILM Endgripping	8719214220198	18-02-2016	Class IIa
	FC25.D04	25G Forceps, Asymmetrical Endgripping	8719214220211	18-02-2016	Class IIa
	FC25.D05	25G Forceps, Eckardt Endgripping	8719214220235	18-02-2016	Class IIa
	FC25.D06	25G Forceps, Kuhn 45° Power Gripping	8719214221904	27-06-2016	Class IIa
	FC25.D07	25G Forceps, Shah Xtra Grip	8719214221959	09-11-2016	Class IIa
	FC27.D03	27G Forceps, ILM Endgripping	8719214222727	03-12-2017	Class IIa
	FC27.D05	27G Forceps, Eckardt Endgripping	8719214220259	18-02-2016	Class IIa
	FC27.D07	27G Forceps, Shah Xtra Grip	8719214221973	09-11-2016	Class IIa
GMDN 63478	Intraocular scissors, probe-like, single-use				
	SC23.D01	23G Scissors, Vertical	8719214220334	18-02-2016	Class IIa
	SC23.D02	23G Scissors, Straight	8719214220358	18-02-2016	Class IIa
	SC23.D03	23G Scissors, Horizontal Curved	8719214220372	18-02-2016	Class IIa
	SC25.D01	25G Scissors, Vertical	8719214220396	18-02-2016	Class IIa
	SC25.D02	25G Scissors, Straight	8719214220419	18-02-2016	Class IIa
	SC25.D03	25G Scissors, Horizontal Curved	8719214220433	18-02-2016	Class IIa
	SC27.D01	27G Scissors, Vertical	8719214220457	18-02-2016	Class IIa
	SC27.D03	27G Scissors, Horizontal Curved	8719214220471	18-02-2016	Class IIa
GMDN 58070*	Vitreotomy contact lens, single-use				
	VL00.D01	Vitreotomy Lens, Flat Style	8719214221287	04-07-2016	Class Is
	VL00.D02	Vitreotomy Lens, Biconcave Style	8719214221263	04-07-2016	Class Is
	VL00.D03	Vitreotomy Lens, Magnifying Style	8719214221249	04-07-2016	Class Is
	VL00.D04	Vitreotomy Lens, Wide View Style	8719214221225	04-07-2016	Class Is
	VL00.D05	Vitreotomy Lens, 30 degree Prism Style	8719214221201	04-07-2016	Class Is

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GMDN 47130	Vitreotomy fluid/gas handling instrument				
	BF23.D01	23G Blunt Backflush Instrument	8719214220815	18-02-2016	Class IIa
	BF23.D02	23G Brush Backflush Instrument	8719214220839	18-02-2016	Class IIa
	BF23.D05	23G Retractable Brush BF-Instrument	8719214220853	18-02-2016	Class IIa
	BF23.D07	23G Extendable Silicone Tipped BF-Instrument	8719214220877	18-02-2016	Class IIa
	TM23.D01	23G Retractable Tissue Manipulator	8719214221829	20-04-2017	Class IIa
	BF25.D01	25G Blunt Backflush Instrument	8719214220891	18-02-2016	Class IIa
	BF25.D02	25G Brush Backflush Instrument	8719214220914	18-02-2016	Class IIa
	BF25.D05	25G Retractable Brush BF-Instrument	8719214220938	18-02-2016	Class IIa
	BF25.D07	25G Extendable Silicone Tipped BF-Instrument	8719214220952	18-02-2016	Class IIa
	TM25.D01	25G Retractable Tissue Manipulator	8719214221843	20-04-2017	Class IIa
	BF27.D01	27G Blunt Backflush Instrument	8719214220976	18-02-2016	Class IIa
	BF27.D02	27G Brush Backflush Instrument	8719214220990	18-02-2016	Class IIa
	BF00.D51	Backflush Reservoirs, Passive	8719214221027	18-02-2016	Class IIa
	BF00.D52	Backflush Reservoirs, Active	8719214221041	18-02-2016	Class IIa
	BF00.D53	Disposable Tubing for Active Aspiration	8719214221065	18-02-2016	Class IIa
	BF23.D51	23G BF Blunt Needles	8719214221126	18-02-2016	Class IIa
	BF23.D52	23G BF Brush Needles	8719214221140	18-02-2016	Class IIa
	BF25.D51	25G BF Blunt Needles	8719214221164	18-02-2016	Class IIa
	BF25.D52	25G BF Brush Needles	8719214221188	18-02-2016	Class IIa
GMDN 46705	Ophthalmic infusion/aspiration cannula, single-use				
	MD23.D01	23G PFC Injection Needle	8719214221362	16-06-2017	Class IIa
	MD25.D01	25G PFC Injection Needle	8719214221386	16-06-2017	Class IIa
	CN23.D03	23G VFI Cannula	8719214221423	16-06-2017	Class IIa
	CN25.D03	25G VFI Cannula	8719214221447	16-06-2017	Class IIa
	CN27.D03	27G VFI Cannula	8719214221461	16-06-2017	Class IIa
	CN23.D01	23G Silicone Tipped Cannula	8719214221508	16-06-2017	Class IIa
	CN25.D01	25G Silicone Tipped Cannula	8719214221522	16-06-2017	Class IIa
	CN23.D04	23G Pick Needles	8719214221584	16-06-2017	Class IIa
	CN25.D04	25G Pick Needles	8719214221607	16-06-2017	Class IIa
	CN23.D05	23G Blunt Needles with luer-lock connector	8719214221621	16-06-2017	Class IIa
	CN25.D05	25G Blunt Needles with luer-lock connector	8719214221645	16-06-2017	Class IIa
	CN27.D05	27G Blunt Needles with luer-lock connector	8719214221669	16-06-2017	Class IIa

*With Class I products placed on the market in sterile condition, the intervention by the notified body is limited to only the aspects of manufacture concerned with securing and maintaining sterile conditions.

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