EC DECLARATION OF CONFORMITY

Manufacturer: Valeant Med Sp. z o.o.
Address: ul. Ryżowa 31, 02-495 Warszawa, POLAND

Product name / Identifier:

Product name	SKU	GTIN
Eyefill H.D. **2.5 ml viscoelastic solution for intraocular use**	Please see Annex 1	

We hereby declare under our exclusive responsibility that the above-named medical device meets all applicable requirements of the Council Directive 93/42/EEC.

List of standards: See Annex 2

Risk class: IIb
Classification Rule: 8
Conformity assessment procedure: Annex II.3

Manufacturing site: CROMA-PHARMA GmbH
Address: Industriezeile 6, 2100 Leobendorf, AUSTRIA

Notified body:
TÜV SÜD Product Service GmbH
Ridlerstrasse 65
80339 München, Germany
Identification number: 0123

Related Certificates:

EN ISO 13485:2016	Q5 093325 0012 Rev. 00	valid until: 17.02.2022
EC Certificate (Annex II.3):	G1 093325 0014 Rev. 00	valid until: 26.05.2024

Version: 09

Declaration valid until: 26.05.2024

Warsaw 28.01.2021

SITE DIRECTOR

Marcin Dębowski, PhD. Eng.

Valeant Med Sp. z o.o.
ul. Ryżowa 31, 02-495 Warszawa
tel: + 48 22 578 16 00
fax: +48 22 578 16 18
NIP: 525-15-55-703 REGON: 012279659
2

Place	Date	Name and Surname/Function	Signature	company stamp

Version: 09

DoC Addendum		
Field Number	**Field Name**	**Field Data**
FLD_DOC_01	Product	Eyefill H.D.
FLD_DOC_02	Legal Manufacturer Name	Valeant Med. Sp. z o.o.
FLD_DOC_03	Single Registration Number	*Not applicable*
FLD_DOC_04	Notified Body Name	TÜV SÜD Product Service GmbH
FLD_DOC_05	Notified Body Number	0123
FLD_DOC_06	Technical File Name	TF-10
FLD_DOC_07	Device Type	Viscoelastic solutions for intraocular applications
FLD_DOC_08	Device Class	IIb
FLD_DOC_09	Basic UDI-DI	**59023159B00104Q**
FLD_DOC_10	DoC name	V_RA_FORM_016_05 (English version) V_RA_FORM_016p_05 (Polish version)
FLD_DOC_11	EC Cert Number	G1093325 0014 Rev. 00
FLD_DOC_12	EC Cert Expiry (DD/MM/YYYY)	26/052024

Product List Included in DoC			
TF No.	**SKU**	**Product name**	**GTIN**
TF-10	EYEFILL-HD-WST	Eyefill H.D. 2.5 ml viscoelastic solution for intraocular use	5902315904408
TF-10	EYEFILL-HD-EST	Eyefill H.D. 2.5 ml viscoelastic solution for intraocular use	5902315908819

No.	Standard Identification	Standard Name
1.	EN 1041	Information supplied by the manufacturer of medical devices
2.	EN 556-1	Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices
3.	EN ISO 10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
4.	EN ISO 10993-3	Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
5.	EN ISO 10993-5	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
6.	EN ISO 10993-6	Biological evaluation of medical devices - Part 6: Tests for local effects after implantation
7.	EN ISO 10993-9	Biological evaluation of medical devices - Part 9: Framework for identification and quantification of potential degradation products
8.	EN ISO 10993-11	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
9.	EN ISO 10993-13	Biological evaluation of medical devices - Part 13: Identification and quantification of degradation products from polymeric medical devices
10.	EN ISO 10993-16	Biological evaluation of medical devices - Part 16: Toxicokinetic study design for degradation products and leachables
11.	EN ISO 10993-17	Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances
12.	EN ISO 10993-18	Biological evaluation of medical devices -- Part 18: Chemical characterization of materials
13.	EN ISO 11138-1	Sterilization of health care products – Biological indicators – Part 1: General requirements
14.	EN ISO 11138-3	Sterilization of health care products - Biological indicators - Part 3: Biological indicators for moist heat sterilization processes
15.	EN ISO 11607-1	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
16.	EN ISO 11607-2	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
17.	EN ISO 11737-1	Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products
18.	EN ISO 11737-2	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
19.	EN ISO 13485	Medical devices - Quality management systems - Requirements for regulatory purposes
20.	EN ISO 14971	Medical devices - Application of risk management to medical devices
21.	EN ISO 15798	Ophthalmic implants - Ophthalmic viscosurgical devices
22.	EN ISO 17665-1	Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices
23.	MEDDEV 2.7/1	Clinical evaluation: Guide for manufacturers and notified bodies

No.	Standard Identification	Standard Name
24.	EN ISO 15223-1	Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements
25.	EN 62366-1	Medical devices – Part 1: Application of usability engineering to medical devices
26.	EN ISO 10993-10	Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
27.	ISO 14644-1	Cleanrooms and associated controlled environments – Part 1: Classification of air cleanliness
28.	ISO 14644-2	Cleanrooms and associated controlled environments – Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration
29.	ISO 14644-3	Cleanrooms and associated controlled environments - Part 3 Test method
30.	ISO 14644-4	Cleanrooms and associated controlled environments - Part 4 Design, construction and start-up.
31.	ISO 14644-5	Cleanrooms and associated controlled environments -- Part 5: Operations
32.	EN ISO 14630	Non-active surgical implants - General requirements
33.	ISO 11040--8	Prefilled syringes – Part 8: Requirements and test methods for finished prefilled syringes