



THE STANDARD Co., Ltd.

120, Gunpocheomdansaneop 2-ro, Gunpo-si, Gyeonggi-do, 15880, Korea
Tel.(02) 838-5533 Fax.(02) 838-5523

www.thestandard.co.kr

DOC. No. : TSLE-DOC-905(Rev.4)

EC Declaration of Conformity

Manufacturer : The Standard Co., Ltd.

120, Gunpocheomdansaneop 2-ro, Gunpo-si, Gyeonggi-do, 15880, Korea

European representative : Certification Experts B.V.

Amerlandseweg 7, 3621 ZC, Breukelen, The Netherlands Tel: +31 (0) 85 007 3220

Product Name : Submucosal Injection Agent

Model name : Blue Eye(TS-905)

Classification : Class IIb by Rule 6 of Annex IX, MDD 93/42/EEC

Conformity Assessment Route: Annex II (excluding Section4)

We herewith declare that the above mentioned products meet the provisions of the Council Directive 93/42/EEC as amended by 2007/47/EC for medical devices. All supporting documentation is retained under the premises of the manufacturer.

•Notified body: SGS Belgium NV

SGS House, Noorderlaan 87, BE-2030 Antwerpen Belgium



Applied standard :

EN ISO 13485:2016, ISO 14971:2019, ISO/TR 24971:2020, ISO/IEC 17050-1, ISO 10993-1:2018, ISO 10993-3:2014, ISO 10993-4:2017, ISO 10993-5:2009, ISO 10993-6:2016, ISO 10993-10:2010, ISO 10993-11:2017, ISO 10993-18:2020, ISO 10993-33:2015, ISO 14644-1:2015, ISO 11607-1:2019, ISO 11607-2:2019, ISO 14698-1:2003, ISO 14698-2:2003, ISO 7886-1:2017, ISO 8036-7:2021, ISO 80369-20:2015, ISO 17665-1:2006, ISO/TS 17665-2:2009, ISO 11138-1:2017, ISO 11138-3:2017, ISO 15223-1:2021, ISO 20417:2021, ISO 11040-6:2019, ISO/TR 20416:2020, ISO 11737-1:2018, ASTM F88M-21, ASTM F1929-15, MEDDEV 2.7/1 Rev.4, USP <85>, USP <151> Pyrogen Test, OECD 471: Bacterial Reverse Mutation Test, OECD 490: In Vitro Mammalian Cell Gene Mutation Test Using the Thymidine Kinase Gene

GMDN Code : 62217

Certificate No. : KR19/81826199

Date of expiry : May. 24, 2024

Place, Date of Declaration : Gyeonggi do, Korea, November, 14, 2023

Name : Seong Nam, Kim

Position : President for The Standard Co., Ltd.