



THE STANDARD Co., Ltd.

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

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DOC. No. : TSBE-DOC-205(Rev.3)

EC Declaration of Conformity

Manufacturer : The Standard Co., Ltd.

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

European representative : AR Experts B.V.

Amerlandseweg 7, 3621 ZC, Breukelen, The Netherlands Tel: +31 889 951 333

Product Name : Black Eye

Model name : TS-205, TS-201

Classification : Class IIb by Rule 7 of Annex IX, MDD 93/42/EEC

Conformity Assessment Route: Annex II (excluding Section 4)

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 10993-5:2009, ISO 10993-6:2016, ISO 10993-10:2021, ISO 10993-11:2017, ISO 10993-12:2021, ISO 10993-18:2020, ISO 14644-1:2015, ISO 14698-1:2003, ISO 14698-2:2003, ISO 11607-1:2019, ISO 11607-2:2019, ISO 17665:2024, ISO 11138-1:2017, ISO 11138-3:2017, ISO 11737-1:2018, ISO 11737-2:2019, ISO 7886-1:2017, ISO 80369-7:2021, ISO 80369-20:2015, ISO 15223-1:2021, ISO 20417:2021, ISO 11040-6:2019, ISO/TR 20416:2020, ASTM F88M-23, ASTM F1929-23, MEDDEV 2.7/1 rev.4

GMDN Code : 17828

Certificate No. : KR19/81826199

Date of expiry : May. 24, 2024

Place, Date of Declaration : Gyeonggi do, Korea, March, 04, 2024

Name : Seong Nam, Kim

Position : President for The Standard Co., Ltd.