

**SENTIENX SDN. BHD.****GOOD HEALTH, SAFETY FIRST & BE HONEST**

Company No.  
200901030154 (873260-D)  
SST ID: K16-1808-22000005

A member of Top Glove Group: The World's Largest Manufacturer of Gloves

**FACTORY 38**

: Lot 7, Jalan Hi-Tech 12, Zon Industri Fasa 3, 09090 Kulim Hi-Tech Park, Kedah D.A., Malaysia.

☎ +603 7890 3338/+603 3362 3098

☎ +6012 2896 270

✉ sales@topglove.com.my

🌐 www.topglove.com

### EU DECLARATION OF CONFORMITY

Manufacturing Site	: SENTIENX SDN. BHD : Lot 7, Jalan Hi-Tech 12, Zon Industry 3, 09090, Kulim Hi-Tech Park Kedah D.A. Malaysia.
European Authorized Representative	: Ulma International GmbH Pfaffenweg 35 89231 Neu-Ulm, Germany
Name of Device	: Sterile Flexylon Surgical Glove
Type	: Powder Free
Device Reference Code (PPER)	: 489-015-1, 5.5 489-015-2, 6.0 489-015-3, 6.5 489-015-4, 7.0 489-015-5, 7.5 489-015-6, 8.0 489-015-7, 8.5 489-015-8, 9.0
Brand Name	: Finessis Zero
Size	: 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0
Classification (MDD)	: Class IIa
Classification (PPER)	: Category III
Conformity Assessment Procedure (MDD)	: Annex II excluding 4
Conformity Assessment Procedure (PPER)	: Annex VII (Module C2)
EU Type Examination Certificate Number (PPER)	: 2777/10574-03/E00-00
EU Type Examination Certificate Issued by (PPER)	: SATRA Technology Europe Limited, Bracetown Business Park, Clonee, D15YN2P, Ireland.
Notified Body Number (PPER)	: 2777
EU Type Examination Certificate (PPER) valid from	: 24th April 2020
EU Type Examination Certificate (PPER) valid until	: 12th June 2023
Notified Body Number (MDD)	: 0123
Notified Body (MDD)	: TÜV SÜD Product Service GmbH, Ridlerstraße 65 80339, Munich, Germany.
EC Certificate Number (MDD)	: G1 061155 0014 Rev. 02
EC Certificate (MDD) valid from	: 19th February 2021
EC Certificate (MDD) valid until	: 26th May 2024

**"TO PREVENT CORRUPTION & BRIBERY. CORRUPTION & BRIBERY IS A CRIME.  
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DP 28/07/20/TGT



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We Sentienx Sdn Bhd herewith declare with our own responsibility that above mentioned product with CE mark;

- i. Meet the provisions of the EC Council Directive 93/42/EEC 14<sup>th</sup> June 1993 concerned medical devices, amended by Council Directive 2007/47/EC. All supporting documentations are retained under the premise of manufacturer (head of Quality department).
- ii. is following to the EU Type Examination and conformity with the provisions of the new PPE Regulations (EU) 2016/425 Category III and, where such is the case, with the national standard transposing harmonized standard no. EN ISO 374-1:2016/Type B, EN 420:2003+A1:2009, EN 374-2:2014, EN 374-4:2013, EN 374-5:2016 (protecting against virus, bacteria and fungi) and EN 16523-1:2015.
- iii. is subject to the procedures set out in Annex VII (Module C2) of the new PPE Regulations (EU) 2016/425 under the supervision of the notified body SATRA Technology Europe Limited, Bracetown Business Park, Clonee, D15YN2P, Ireland.

Applicable standards under MDD :

No	Standard	Descriptions	Date Published
1	EN 455-1:2020	Medical gloves for single use. Part 1: Requirement and testing for freedom from holes.	May 2020
2	EN 455-2:2015	Medical gloves for single use. Part 2: Requirement and testing for physical properties.	April 2015
3	EN 455-3:2015	Medical gloves for single use. Part 3: Requirement and testing for biological evaluation.	April 2015
4	EN 455-4:2009	Medical gloves for single use. Part 4: Requirements and testing for shelf life determination.	October 2009
5	EN ISO 14971:2019	Medical device - Application of risk management to medical device.	December 2019
6	ISO 2859-1:2011	Sampling procedures and table for inspection by attributes	June 2011
7	ISO 11737-1:2018/AMD 1:2021	Sterilization of medical device - Microbiological methods estimation of population of microorganisms on product - Amendment 1	May 2021
8	ISO 11737-2:2019	Sterilization of medical device - Microbiological methods - Test of sterility performed I the validation of a sterilization process.	December 2019
9	ISO 11137-1:2015	Sterilization of health care products - Requirements for validation and routine control - Radiation sterilization	July 2015
10	ISO 11137-2:2013	Sterilization of health care products - Establishing the sterilization dose	June 2013
11	ISO 10993-1:2018	Biological evaluation for medical device - Evaluation & Testing	August 2018



**Sentienx****TOP QUALITY, TOP EFFICIENCY****SENTIENX SDN. BHD.****GOOD HEALTH, SAFETY FIRST & BE HONEST**

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No	Standard	Descriptions	Date Published
12	ISO 10993-5:2009	Biological evaluation of medical devices – Tests for in vitro cytotoxicity	June 2009
13	ISO 10993-10:2010	Biological evaluation for medical device - Tests for irritation and delayed-type hypersensitivity.	August 2010
14	ISO 10993-12:2021	Biological evaluation for medical device - Sample preparation and reference materials	Jan 2021
15	EN ISO 11607-1:2020	Packaging for terminally sterilized medical devices - Requirements for materials, sterile barrier systems and packaging systems.	Jan, 2020
16	EN ISO 11607-2:2020	Packaging for terminally sterilized medical devices - Validation requirements for forming, sealing and assembly processes.	Jan, 2020
17	ISO 15223-1:2021	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied Part 1: General requirements.	July 2021
18	EN 62366-1:2015	Medical devices Part 1: Application of usability engineering to medical devices	April, 2015
19	MEDDEV 2.1/1	2.1/1 Definition of Medical Device, Accessory and Manufacturer	April 1994
20	MEDDEV 2.4/1	2.4/1 Classification of Medical Device	Revision 9, June 2010
21	MEDDEV 2.5.1/Rec 1	2.5.1 Technical Documentation	Revision 4, February 2000
22	MEDDEV 2.5/5	2.5/5 Translation Procedure	Revision 3, February 1998
23	MEDDEV 2.5/9	2.5/9 Implication of the Medical Device Directive 9342EEC in Relation to Medical Device Containing Natural Rubber Latex	Revision 1, February 2004
24	MEDDEV 2.5/10	2.5/10 Guideline for Authorized Representative	January 2010
25	MEDDEV 2.7/1	2.7/1 Clinical Evaluation	Revision 4, June 2016
26	MEDDEV 2.12/1	2.12/1 Medical Device Vigilance System	Revision 8, January 2013
27	MEDDEV 2.12/2	2.12/2 Post Market Clinical Follow-up Studies	Revision 2, January 2012
28	MEDDEV 2.12/Rec 1	2.12 Post - Marketing Surveillance (PMS) post market / production	Revision 11, February 2000

DoC Issue Date

: 8<sup>th</sup> November 2022

  
 Name: Ph Noor Akilah Saidin  
 Designation: RA General Manager  
 RA/DOC/MDDPPE/STX/FNZR/10/001/12/22/R1



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