EU DECLARATION OF CONFORMITY

Name of Device: Flexylon Sterile Surgical Powder Free Gloves

Manufacturing Site
Sentienx Sdn. Bhd.
Lot 7, Jalan Hi-Tech 12, Zon Industri Fasa 3,
09090 Kulim Hi-Tech Park, Kedah D.A., Malaysia

MDR 2017/745

Single Registration Number	: MY-MF-000023461 (Manufacturing Site SRN)
European Authorized Representative	: Ulma International GmbH Alfred-Nobel-Straße 5, 50226 Frechen, Germany.
Single Registration Number	: DE-AR-000010015 (EAR SRN)
Classification Rule	: Rule 7, Class IIa
Conformity Assessment Procedure	: Annex IX (Chapter I)
Basic UDI – DI	: 955100594000CU
Brand name	: Peha Skin
EC Certificate(s) number	: G15 090719 0014 Rev. 00
EC Certificate(s) valid until	: 02-07-2030
Notified Body	: TÜV SÜD Product Service GmbH, Ridlerstraβe 65, 80339, Munich, Germany.
CE Marking	: CE 0123
Applicable Standards	: Attachment I

Intended use: Sterile Flexylon Surgical Powder Free Gloves is used as a biological barrier to protect the user's hands against contamination. The gloves are designed to come into contact with the patient and prevent cross-contamination between patient and user.

PPER 2016/425

Classification	: Category III
Conformity Assessment Procedure	: Annex V (Module B) and Annex VII (Module C2)
EU Type Examination Certificate Number	: 2777/10577-03/E01-01
EU Type Examination Notified Body	: SATRA Technology Europe Limited, Bracetown Business Park, Clonee, D15YN2P, Ireland.
CE Marking	:CE 2777

Intended Use:
Sterile Flexylon Surgical Powder Free Gloves is used as a biological barrier to protect the user's hands against contamination. The gloves are designed to come into contact with the patient and prevent cross-contamination between patient and user.

Disclaimer: This Declaration of Conformity applicable only to the specified brand and products produced at the mentioned premises. Any unauthorized use including but not limited to reproduction, dissemination, distribution, printing or copy of this document is strictly prohibited and may result in legal action.
"TO PREVENT CORRUPTION & BRIBERY, CORRUPTION & BRIBERY IS A CRIME. BE HONEST AND NO CHEATING"
DP 28/07/20/TGT

Conclusion:

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

I. Meet the provision of the Regulation (EU) MDR 2017/745 for medical devices. This declaration is also supported by the Quality Management System approval to ISO 13485 issued by TÜV SÜD Product Service GmbH. All supporting documentation is retained at the premises of the manufacturer.

IIa. Meet to the EU Type Examination and conformity with the provisions of the new PPE Regulations (EU) 2016/425 Category III, Annex V (Module B) and, where such is the case, with the national standard transposing harmonized standard no. EN ISO 21420:2020, EN ISO 374-1:2016+A1:2018 (EN ISO 374-2:2019, EN 16523-1:2015+A1:2018, EN ISO 374-4:2019), EN ISO 374-5:2016, EN ISO 374-5:2016 and EN 421:2010 (excluding clause 4.3).

IIb. The product 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.

DoC Validity Date : 25th November 2025 – 24th November 2027

Name: Noor Akilah Saidin
Designation: General Manager, RA
Date: 25/11/2025

Disclaimer: This Declaration of Conformity applicable only to the specified brand and products produced at the mentioned premises. Any unauthorized use including but not limited to reproduction, dissemination, distribution, printing or copy of this document is strictly prohibited and may result in legal action.

ATTACHMENT I: LIST OF APPLICABLE STANDARDS AND REFERENCE FOR MDR 2017/745

No	Standard	Descriptions	Date Published
1	EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)	March 2016
2	EN 455-1:2020+A2:2024	Medical gloves for single use. Part 1: Requirement and testing for freedom from holes.	September 2024
3	EN 455-2:2024	Medical gloves for single use. Part 2: Requirement and testing for physical properties.	May 2024
4	EN 455-3:2023	Medical gloves for single use. Part 3: Requirement and testing for biological evaluation	December 2023
5	EN 455-4:2009	Medical gloves for single use - Part 4: Requirements and testing for shelf life determination	October 2009
6	EN ISO14971:2019/A11:2021	Medical device - Application of risk management to medical devices.	December 2021
7	ISO 2859-1:2011	Sampling procedures for inspection by attributes – Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection	June 2011
8	EN ISO 11737-1:2018/ A1:2021	Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products (ISO 11737-1:2018)	June 2021
9	EN ISO 11737-2:2020	Sterilization of health care products - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process (ISO 11737-2:2019)	May 2020
10	EN ISO 11137-1:2015/ A2:2019	Sterilization of health care products – Requirements for validation and routine control–Radiation sterilization	November 2019
11	EN ISO 11137-2:2015	Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose (ISO 11137-2:2013)	June 2015

Disclaimer: This Declaration of Conformity applicable only to the specified brand and products produced at the mentioned premises. Any unauthorized use including but not limited to reproduction, dissemination, distribution, printing or copy of this document is strictly prohibited and may result in legal action.

No	Standard	Descriptions	Date Published
12	EN ISO 10993-1:2020	Biological evaluation for medical device – Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2018)	December 2020
13	EN ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009)	June 2009
14	EN ISO 10993-10:2013	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization (ISO 10993-10:2010)	August 2013
15	EN ISO 10993-11:2018	Biological evaluation of medical devices. Test for systemic toxicity (ISO 10993-11:2017)	May 2018
16	EN ISO 10993-12:2021	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials (ISO 10993-12:2021)	June 2021
17	EN ISO 10993-23:2021	Biological evaluation of medical devices - Part 23: Tests for irritation (ISO 10993-23:2021)	March 2021
18	EN ISO 11607-1:2020	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2019)	January 2020
19	EN ISO 11607-2:2020	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607-2:2019)	January 2020
20	EN ISO 15223-1:2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements (ISO 15223-1:2021)	September 2021
21	EN 62366-1/A1:2020	Medical Devices – Part 1: Application of usability engineering to medical devices	August 2020
22	EN ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer (ISO 20417:2021)	May 2021
23	ISO/TR 20416:2020	Medical devices — Post-market surveillance for manufacturers	July 2020
24	ASTM D4169-16	Standard Practice for Performance Testing of Shipping Containers and Systems	April 2016
25	MDR 2017/745 (Annex VIII)	Classification rules	April 2017
26	MDR 2017/745 (Annex I)	Technical Documentation	April 2017
27	MDR 2017/745 (Annex XIV: Part A)	Clinical Evaluation	April 2017

Disclaimer: This Declaration of Conformity applicable only to the specified brand and products produced at the mentioned premises. Any unauthorized use including but not limited to reproduction, dissemination, distribution, printing or copy of this document is strictly prohibited and may result in legal action.

No	Standard	Descriptions	Date Published
28	MEDDEV 2.7/1	2.7/1 Clinical Evaluation	Revision 4, June 2016
29	MEDDEV 2.12/1	2.12/1 Medical Device Vigilance System	Revision 8, January 2013
30	MDR 2017/745 (Chapter VII: Section 2: Article 87-92)	Vigilance	April 2017
31	MDR 2017/745 (Annex XIV: Part B)	Post Market Clinical Follow-up Studies	April 2017
32	MEDDEV 2.12/2	2.12/2 Post Market Clinical Follow-up Studies	Revision 2, January 2012
33	MDR 2017/745 (Chapter VII: Section 1: Article 83-86) Annex III	Post Marketing Surveillance (PMS)	April 2017

Disclaimer: This Declaration of Conformity applicable only to the specified brand and products produced at the mentioned premises. Any unauthorized use including but not limited to reproduction, dissemination, distribution, printing or copy of this document is strictly prohibited and may result in legal action.