

## EC Declaration of Conformity to the 93/42/EEC Medical Device Directive

Isol8 Healthcare Ltd declare under our sole responsibility that the medical device specified in the Appendix 1 meets all provisions of the Medical Device Directive 93/42/EEC and all relevant modifying Directives.

<b>Manufacturer:</b>	<b>ISOL8 Healthcare Ltd</b>
<b>Address:</b>	<b>Unit 4 Joyce House, Ballincollig, Co. Cork, Ireland, P31 HW35</b>
<b>Device:</b>	<b>Surgical gown</b>
<b>Device Classification:</b>	<b>Class Is under Rule 1</b>
<b>CE marking first applied:</b>	<b>05 May 2021</b>
<b>GMDN code and term:</b>	<b>35091, Surgical gown, single use</b>

This Declaration of Conformity is issued on the basis of fulfilment of requirements of Annex I and Annex V of the Council Directive 93/42/EEC:

- Quality Management System certification to ISO 13485:2016 under the supervision of ICIM SpA
- EC Certificate No. 0425-MED-004388-00 issued by ICIM SpA
- Availability of technical documentation per Annex VII of the Medical Device Directive.

### Standards applied:

- EN ISO 14971:2019
- EN 13795-1:2019
- EN ISO 11135:2014
- EN 556-1:2001
- EN ISO 11607-1 and -2:2019
- EN ISO 11737-1:2018
- EN ISO 11737-2:2019
- EN ISO 11138-1 and -2:2017
- EN 14644-1:2015
- EN 14698-1:2003
- EN ISO 10993-1:2018
- EN ISO 10993-5:2013
- EN ISO 10993-7:2008
- EN ISO 10993-10:2013
- ISO 15223-1:2021
- EN ISO 20417:2021

Authorised Signatory:



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Date: 1<sup>st</sup> August 2022

Dr Fergal Whitehead,

Place: Cork

Director of Operations of ISOL8 Healthcare Ltd

## Appendix I

### List of devices, components and accessories

#### Basic UDI-DI - 539154127IS88SGBZ

ID	Trade Name	Class/Rule	UDI-DI
IS8E01	Elemental Standard Surgical Gown M	Class Is/ Rule 1	05391541270003
IS8E02	Elemental Standard Surgical Gown L	Class Is/ Rule 1	05391541270010
IS8E03	Elemental Standard Surgical Gown XL	Class Is/ Rule 1	05391541270027
IS8E04	Elemental Standard Surgical Gown XL – Long	Class Is/ Rule 1	05391541270041
IS8E05	Elemental Standard Surgical Gown 2XL	Class Is/ Rule 1	05391541270058
IS8E06	Elemental Standard Surgical Gown 2XL – Long	Class Is/ Rule 1	05391541270065
IS8E07	Elemental Standard Surgical Gown 3XL	Class Is/ Rule 1	05391541270072
IS8E08	Elemental Poly-Reinforced Surgical Gown M	Class Is/ Rule 1	05391541270089
IS8E09	Elemental Poly-Reinforced Surgical Gown L	Class Is/ Rule 1	05391541270096
IS8E10	Elemental Poly-Reinforced Surgical Gown XL	Class Is/ Rule 1	05391541270102
IS8E11	Elemental Poly-Reinforced Surgical Gown XL–Long	Class Is/ Rule 1	05391541270119
IS8E12	Elemental Poly-Reinforced Surgical Gown 2XL	Class Is/ Rule 1	05391541270126
IS8E13	Elemental Poly-Reinforced Surgical Gown 2XL–Long	Class Is/ Rule 1	05391541270133
IS8E14	Elemental Poly-Reinforced Surgical Gown 3XL	Class Is/ Rule 1	05391541270140
IS8P01	Plush Standard Surgical Gown M	Class Is/ Rule 1	05391541270157
IS8P02	Plush Standard Surgical Gown L	Class Is/ Rule 1	05391541270164
IS8P03	Plush Standard Surgical Gown XL	Class Is/ Rule 1	05391541270171
IS8P04	Plush Standard Surgical Gown XL – Long	Class Is/ Rule 1	05391541270188
IS8P05	Plush Standard Surgical Gown 2XL	Class Is/ Rule 1	05391541270195
IS8P06	Plush Standard Surgical Gown 2XL – Long	Class Is/ Rule 1	05391541270201
IS8P07	Plush Standard Surgical Gown 3XL	Class Is/ Rule 1	05391541270218
IS8P08	Plush Poly-Reinforced Surgical Gown M	Class Is/ Rule 1	
IS8P09	Plush Poly-Reinforced Surgical Gown L	Class Is/ Rule 1	
IS8P10	Plush Poly-Reinforced Surgical Gown XL	Class Is/ Rule 1	
IS8P11	Plush Poly-Reinforced Surgical Gown XL – Long	Class Is/ Rule 1	
IS8P12	Plush Poly-Reinforced Surgical Gown 2XL	Class Is/ Rule 1	
IS8P13	Plush Poly-Reinforced Surgical Gown 2XL – Long	Class Is/ Rule 1	
IS8P14	Plush Poly-Reinforced Surgical Gown 3XL	Class Is/ Rule 1	
IS8S01	Supreme Impervious Surgical Gown L	Class Is/ Rule 1	05391541270225
IS8S02	Supreme Impervious Surgical Gown XL	Class Is/ Rule 1	05391541270232
IS8S03	Supreme Impervious Surgical Gown XL – Long	Class Is/ Rule 1	05391541270249
IS8S04	Supreme Impervious Surgical Gown 2XL	Class Is/ Rule 1	05391541270256
IS8S05	Supreme Impervious Surgical Gown 2XL – Long	Class Is/ Rule 1	05391541270263
IS8S06	Supreme Impervious Surgical Gown 3XL	Class Is/ Rule 1	05391541270270