

EU DECLARATION OF CONFORMITY

Manufacturer name and address: Shamrock Manufacturing Co., Inc.
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SRN (Single Registration Number): N/A

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We, Shamrock Manufacturing Co., Inc., hereby declare under our sole responsibility that the devices listed in the attached Annex comply with the provisions of the REGULATION (EU) 2017/745.

The devices are Class I following Rule 5 of Annex VIII of REGULATION (EU) 2017/745.

The Conformity Assessment Procedure has been performed following Art. 19 and Art. 52 (7), and Technical Documentation was drawn up following Annex II and III of the Regulation (EU) 2017/745.

The following Standards have been used and in relation to which conformity is declared:

EN 420:2003+A1:2009 / EN ISO 374-1:2016 / EN ISO 374-5:2016
EN 455 - 1, 2, 3
ISO 13485:2016

We hereby also declare under our sole responsibility that the devices Shamrock Latex Examination Gloves Pre-Powdered and Shamrock Latex Examination Gloves Powder Free, respectively items #2 and #6 listed in the annex below, comply with the provisions of Regulation (EU) 2016/425.

The Conformity assessment was performed according to Annex III under surveillance of the Notified Body Centexbel, No. 0493.

The Notified Body Centexbel No. 0493 performed the EU-type examination and issued the EU-Type examination certificate: 062/2019/0147 (Date of issuance: 25 January 2019; Date of expiry: 25 January 2024).



Jeni Chuason
 Regulatory Affairs Specialist

Chino, California December 28, 2021

Annex - List of Devices Covered by the Declaration of Conformity

#	Commercial name/ Trade name	Model/ Reorder/ Catalogue no.#	Description	Intended Purpose	Class	Classific. rule applied	BASIC UDI - DI	GMDN/E MDN code
1	Shamrock Latex Examination Gloves Pre-Powdered	T11110	Pre-Powdered, Non-Sterile Latex Examination Gloves	A patient examination glove is a disposable device intended for medical purpose that is worn on examiner's hand to prevent contamination between patient and examiners.	I	Rule 5	0641932SMC LPP110BF	47173 / T010201
		T11111						
2	Shamrock Latex Examination Gloves Pre-Powdered	T11112						
		T11113						
3	MyGuard Latex Examination Gloves Pre-Powdered	T11114						
		MG-2100						
4	Protos Latex Examination Gloves Pre-Powdered	MG-2101						
		MG-2102						
5	Shamrock Latex Examination Gloves Powder Free	MG-2103	Powder Free, Non-Sterile Latex Examination	A patient examination glove is a disposable	I	Rule 5	0641932SMC LPF10096	47172 / T010201
		MG-2104						
		E9200						
		E9201						
		E9202						
		E9203						
		E9204						

		T10114	Gloves	device intended for medical purpose that is worn on examiner's hand to prevent contamination between patient and examiners.				
6	Shamrock Latex Examination Gloves Powder Free	10110 10111 10112 10113 10114						
7	MyGuard Latex Examination Gloves Powder Free	MG-2200 MG-2201 MG-2202 MG-2203 MG-2204						
8	Protos Latex Examination Gloves Powder Free	E8200 E8201 E8202 E8203 E8204						
9	Shamrock SUPREME Nitrile Examination Gloves Powder Free	30350 30351 30352 30353 30354 30355	Powder Free, Non-Sterile Nitrile Examination Gloves	A patient examination glove is a disposable device intended for medical purpose that is worn on examiner's hand to prevent contamination between patient and examiners.	I	Rule 5	0641932SMC LPP300AA	56286 / T010202 04
10	MyGuard Nitrile Examination Gloves Powder Free	MG-3030 MG-3031 MG-3032 MG-3033 MG-3034						