MY TICARET VE MEDIKAL A.S.
Ömerli Mahallesi General Şükrü Koraltı Caddesi No:33 Arnavutkoy –Istanbul Turkey
Tel: +902124382064 Fax: +902124382065
Website: www.mymedikal.com.tr.

EU DECLARATION OF CONFORMITY

EC Certificate	Not applicable (Self- declared)
Manufacturer	MY TICARET VE MEDIKAL A.S.
Manufacturer Address	Ömerli mah General Şükrü Koraltı Cd no:33, 3455 Arnavutkoy/Istanbul, Turkey
Single Registration Number (SRN)	TR-MF-000018372
Brand	Sente
Product Description & Registration/Reference No.	Powderfree Latex Examination Gloves
Intended Purpose	A patient examination glove is a medical device intended for a medical purpose that is worn on the examiners hand or finger to prevent contamination between patient and examiner. Examination glove is intended for medical activities except surgery.
Basic UDI-DI	868302002LPFLR
Size	S, M, L, XL
European Medical Device Nomenclature (EMDN)	T010201 (Examination/Treatment Gloves, Latex)
Global Medical Device Nomenclature (GMDN)	47172 (Latex Examination/treatment glove, non-powdered, non-sterile)
Product Catalogue Number	SELPF01-S, SELPF02-M, SELPF03-L, SELPF04-XL
Classification & Rule (MDR)	Class I, Non Sterile, Rule 5
Conformity Assessment Route:	Annex I and Annex II and Annex IV
Applicable Standards	EN ISO 13485:2016; EN ISO 9001:2015; EN 455-1:2020; EN 455-2:2015; EN 455-3:2015; EN 455-4:2009; EN ISO 14971:2019; EN 62366-1:2015; ISO 2859-1:2011; ISO 10993-1:2018; ISO 10993-5:2009; EN ISO 10993-10:2013; EN ISO 10993-11:2018; ISO 10993-12:2012; EN ISO 15223-1:2011; MDR 2017/745 (Annex I: Chapter 2, Chapter I: Article 2, Annex VIII, Annex II, Chapter II: Article 11&12, Annex XIV: Part A, Chapter VII: Section 1: Article 83-86 Annex III), MEDDEV 2.7/1, MEDDEV 2.12-1 rev 8, MEDDEV 2.12/1, MEDDEV 2.12/Rec 1, EN 1041:2008 + A1 2013, ISO 10993-23:2021

We, My Ticaret ve Medikal A.S. herewith declare that the above-mentioned device:

- Is in compliance with the General Safety Performance Requirement of the Medical Device

Regulation (MDR) 2017/745. All supporting documentations are retained under the premise of manufacturer.

- The gloves manufacture according to EN ISO 9001:2015 and EN ISO 13485:2016 Quality Management System:

Verification Certificates: EN ISO 13486:2016 Quality Management System
Certificate No: ISO 02 836 1179

EN ISO 9001:2015 Quality Management System
Certificate No.: ISO 01 940 1179

- This EU Declaration of Conformity is prepared in accordance to Annex IV of Medical Device Regulation (EU) 2017/745.

Authorized Signatory:

Approver : MURAT YILDIZ

Title : General Manager/CEO

Signature :

Approval Date : 13.07.2022

Place of Approval : Istanbul, Turkey

CE