



EC Declaration of Conformity

Version 2
from 25.05.2021

The organisation hereby declares under the registered trade name of

SFM Hospital Products GmbH, Segelfliegerdamm 67-89, 12487 Berlin

with the SRN

DE-MF-000005505

(pursuant to Article 31 of Regulation (EU)2017/745), under our sole responsibility, that the product identified below, as placed on the market by us, complies with Regulation 2017/745 and, where applicable, with other relevant Union legislation providing for the drawing up of an EU declaration of conformity.

A CE conformity marking in accordance with Chapter II, Article 20 and Annex V of Regulation (EU)2017/745 shall be affixed to the product and packaging for

Product name:

Examintion gloves vinyl, powder free

Inted use:

For use during medical examinations to protect the patient.

Item no.:

4036534635834	Clear Vinyl Exam. Gloves, 4,0gr., powder-free, nonsterile Size XS
4036534635049	Clear Vinyl Exam. Gloves, 5,5 gr., powder-free, nonsterile Size XS
4036534636831	Clear Vinyl Exam. Gloves, 4,0gr., powder-free, nonsterile Size S
4036534636046	Clear Vinyl Exam. Gloves, 5,5 gr., powder-free, nonsterile Size S
4036534637838	Clear Vinyl Exam. Gloves, 4,0gr., powder-free, nonsterile Size M
4036534637043	Clear Vinyl Exam. Gloves, 5,5 gr., powder-free, nonsterile Size M
4036534638835	Clear Vinyl Exam. Gloves, 4,0gr., powder-free, nonsterile Size L
4036534638040	Clear Vinyl Exam. Gloves, 5,5 gr., powder-free, nonsterile Size L
4036534639832	Clear Vinyl Exam. Gloves, 4,0gr., powder-free, nonsterile Size XL
4036534639047	Clear Vinyl Exam. Gloves, 5,5 gr., powder-free, nonsterile Size XL
4036534634837	Clear Vinyl Exam. Gloves, 4,0gr., powder-free, nonsterile Size XXL
4036534634042	Clear Vinyl Exam. Gloves, 5,5 gr., powder-free, nonsterile Size XXL



EC Declaration of Conformity

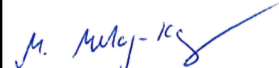
Version 2
from 25.05.2021

Regulation	REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 concerning medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC		
Classification	I	according to Annex VIII	Rule 1
Basic - UDI - DI	04036534VEGQS		
UMDNS Code:	11-882		
MD/ MDS Code:	MD 1214	MDS 0	MDT 2002

Inspection organisation	DEKRA Certification GMBH; Handwerkerstraße 15, 70565 Stuttgart, Deutschland		
Certificate No.:	50759-14-01		
Initial certification:	18.03.2003		
Valid until:	12.03.2025		

In the event of any non-coordinated modification of the products, this declaration of conformity shall lose its validity.

This Declaration of Conformity has been prepared and signed by the Person Responsible for Regulatory Compliance (VPER) on behalf and in the name of the senior management of the organisation SFM Hospital Products GmbH.

01.03.2022	 Marion Metag - Karg
Berlin	Signum VPER