



SAFESHIELD INDIA RUBBER PRODUCTS PVT. LTD.
AN ISO 13485 : 2016 Certified Company CIN-U25191KL1998PTC012350

Plot No. 16-B, CSEZ, Kakkanad, Cochin- 682037, Kerala, India
+91 484-2413174, 2413192, 4058175
sales@safeshieldindia.com, accounts@safeshieldindia.com

EC DECLARATION OF CONFORMITY (DoC)		Doc # SIRP-TF-01-DOC-02
Annex II, Regulation (EU) Directive 93/42/EEC concerning Medical devices.		Issue No. & Dt: 01 / 01-04-2019
		Rev. No. & Dt: 02 / 28-10-2021
Name of the Manufacturer	Safeshield India Rubber Products Pvt. Ltd.	
Address	Plot No. 16B, Cochin Special Economic Zone, Kakkanad, Ernakulam, Kerala, 682037, India Customer care: +91 9846092780	
Device Description	Sterile Latex Surgical gloves Powder Free <i>Generic name: Surgical gloves Powder Free</i>	
EUDAMED SRN #	SE - AR - 000003015	
Sterile or Non-Sterile	Sterile	
Intended Use	The single use Sterile Latex Surgical Gloves-Powder Free is intended for use in Invasive Surgical procedures and to be worn once and then discarded. The glove is worn on the hand of healthcare personnel to prevent contamination between healthcare personnel and the patient's body, fluids, waste or environment. The gloves are designed for transient use (less than 60 minutes) and are intended to be used in conjunction with invasive surgical procedures.	
Device Classification & Justification Regulation (EU) 2017/745, Annex VIII	Class IIa (Rule 6) <i>(Regulation (EU)93/42/EEC on Medical Device)</i> <i>All surgically invasive devices intended for transient use are classified as classIIa</i>	
Details of the notified body which carried out the conformity assessment procedure:	POLISH CENTRE FOR TESTING AND CERTIFICATION (PCBC)(POLSKIE CENTRUM BADAN I CERTYFIKACJI S.A.) ul. Puławska 469 02-844 Warszawa Country :Poland Notified Body number: 1434	
- EU Authorized Representative - EUDAMED Code - Competent Authority	<ul style="list-style-type: none">MEDITA TRADING AB Post box: 56521-17, Skaraborgsgatan 3, 56531, Mullsjo, Sweden Tel + 46 76 318 31 87 Email: info@meditatrading.com / medita.sweden@gmail.com Website: www.meditatrading.comEUDAMED SRN # SE-AR-000003015CA:- Swedish Medical Products Agency, Kingdom of Sweden	



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Manufacturer's Declaration

We, hereby declare under our sole responsibility that, the device name and its variants mentioned below in this DoC is in conformity with the relevant provisions of standards and other normative documents(s) and fulfils the general requirements of safety and performance.

Product Description:

Sl.	Name	Type	Size	Brand	Class	Rule
01	Sterile Latex Surgical Gloves (Powder Free)	Sterile	6.0 6.5 7.0 7.5 8.0 8.5	Armour, Safeglove, Net Care, Heuer, Surgigold, Pharma Care	Class IIa	Rule 6

PRODUCT IMAGE





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The following harmonized & non-harmonized standards were used to prove the product conformity with the essential requirements of the above Directive:

ASTM D3577 - 19	Standard Specification for Rubber Surgical Gloves
EN 455-1:2000	Medical gloves for single use. Requirements and testing for freedom from holes
EN 455-2:2015	Medical gloves for single use. Requirements and testing for physical properties
ISO 13485:2016	Medical devices. Quality management systems. Requirements for regulatory purposes
ISO 14971:2019	Medical devices. Application of risk management to medical devices
ISO 15223-1:2021	Symbols to be used with medical device labels, labeling and information to be supplied. General requirements
ISO 10282- 2023	Specifies requirements for packaged sterile rubber gloves intended for use in surgical procedures to protect the patient and the user from cross-contamination

SIGNATURE :



NAME :

ANIKUMAR P C

DESIGNATION :

MANAGING DIRECTOR

DATE :

12-10-2023

PLACE OF ISSUE :

KAKKANAD, KERALA, INDIA