



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-07&08
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	Non Sterile Examination gloves Powdered Non Sterile Examination gloves Powder free	
EUDAMED SRN #	SE - AR - 000003015	
Sterile or Non-Sterile	Non Sterile	
Intended Use	The single use Non Sterile Latex Examination Gloves Powdered is intended for Medical Examination procedure (not surgically) 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). The single use Non Sterile Latex Examination Gloves-Powder Free is intended for used Medical Examination procedures (not surgically) 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).	
Device Classification & Justification	Class I	



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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	Latex Examination Gloves (Powdered)	Non Sterile	X-Small	Armour,	Class I	Rule 6
			Small	Safeglove,		
02	Latex Examination Gloves (Powder Free)		Medium	Net Care,		
			Large	Heuer,		
			X-Large	Surgigold, PharmaCare		

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 D3578 - 19	Standard Specification for Rubber Examination 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

SIGNATURE :

NAME :

ANIKUMAR P C

DESIGNATION :

MANAGING DIRECTOR

DATE :

12-10-2023

PLACE OF ISSUE :

KAKKANAD, KERALA, INDIA



www.safeshieldindia.com, www.safeshieldindia.net

