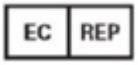
EU DECLARATION OF CONFORMITY

To the 2017/745 Medical Device Regulation

2016/425 Personal Protective Equipment Regulation

Doc No.: DOC-NBR-001

Manufacturer & Address:		Shijiazhuang Hongray Group Co., Ltd. South Tongda Rd., East Dist. Jinzhou, 052260 Hebei, China
Manufacturer SRN Number:		CN-MF-000024227
European Authorized Representative:		Caretechion GmbH Niederrheinstr. 71, 40474 Düsseldorf, Germany
European Authorized Representative SRN Number:		DE-AR-000005946
Basic UDI:	69487944 NPF500X 66	
Product & identification:	Disposable Nitrile Examination Gloves Peha-soft Nitrile White XS: 942030 (NPF5001) Peha-soft Nitrile White S: 942031 (NPF5002) Peha-soft Nitrile White M: 942032 (NPF5003) Peha-soft Nitrile White L: 942034 (NPF5004) Peha-soft Nitrile White XL: 942035 (NPF5005)	
Intended Purpose of the product:	Peha-soft Nitrile White Glove is a disposable product intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.	
GMDN Code:	56286 Nitrile examination/treatment glove, non-powdered, non-antimicrobial	
EMDN Code:	T01020204 Nitrile examination / treatment gloves	
Risk Classification:	Class 1	

We hereby declare that the above mentioned devices comply with the European Medical Device Regulations (EU) MDR 2017/745. The EU declaration of conformity is issued under the sole responsibility of the Manufacturer.

We hereby declare that our EU Type Examination Certificate conformity the requirements of Annex V (Module B) of the regulation (EU)2016/425 of the European Parliament and of the council. Follow the EU Type-Examination the product has been shown to satisfy the applicable essential health and safety requirements of Annex of the PPE

Regulation (EU)2016/425 as a Category III product. The declaration of conformity is issued under the sole responsible of manufacturer.

The Personal Protective Equipment is subject to the conformity assessment procedure conformity to type based on quality assurance of the production process (module D) under surveillance of the notify body SATRA Technology Europe Limited (2777)

Conformity Assessment Procedure:	MDR Article 52(7)
	PPE Article 19 (c,i)
Relevant Harmonized Standards:	EN 455-1:2020 + A1:2022
	EN455-2:2015
	EN455-3:2015
	EN455-4:2009
	EN ISO 21420:2020
	EN ISO 374-1:2016 + A1:2018
	EN 374-2:2019
	EN 16523-1:2015 + A1:2018
	EN ISO 374-4:2019
	EN ISO 374-5:2016
EU Type-Examination Certificate:	2777/14615-03/E00-00
EN 455 Standard Test Report:	TTCN 123687 0002 Rev. 00
	7191313958-EEC23-WBH
EN 374 Standard Test Report:	SPC0293884/2003/Issue 3
	CHM0328557/2212/JH/A
	CHM0328557/2212/JH/B
	CHM0328557/2212/JH/C
	CHT0317652/2132/Issue 2
	CHT0293606/2002/2/Issue 2
Notifying Body:	SATRA Technology Europe Ltd,
	Bracetown Business Park, Clonee, Dublin 15
	Ireland (Notified Body Number: 2777)

Quality System ISO9001 Certificate:	01 100 1732303
Quality System ISO13485:2016 Certificate:	SX 2174809-1

Place and date of issue of the declaration:	Shijiazhuang, China Aug 28, 2024
Signed by:	Wu Min
Name:	Wu Min
Function of the person who signed it:	QA Director
Sign on behalf of the Legal Manufacturer:	Shijiazhuang Hongray Group Co., Ltd.