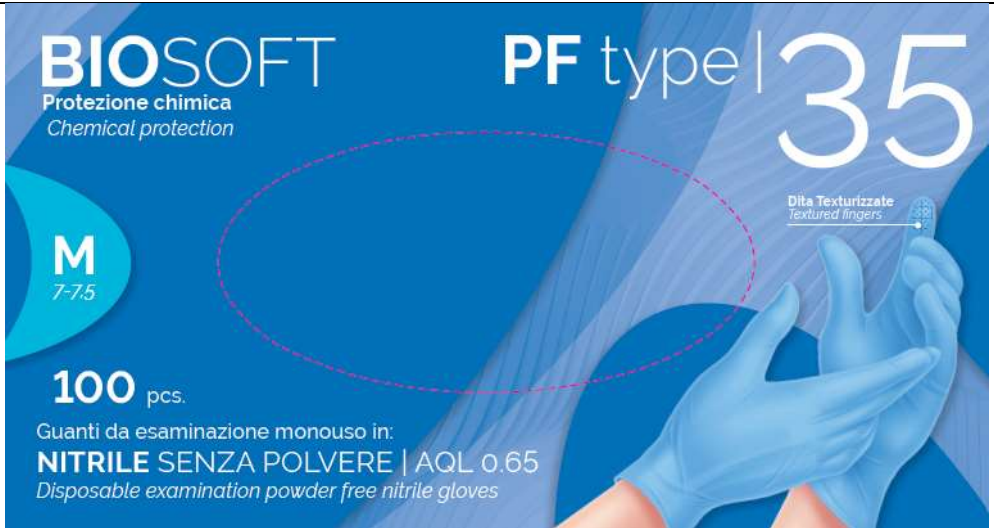


TECHNICAL FILE

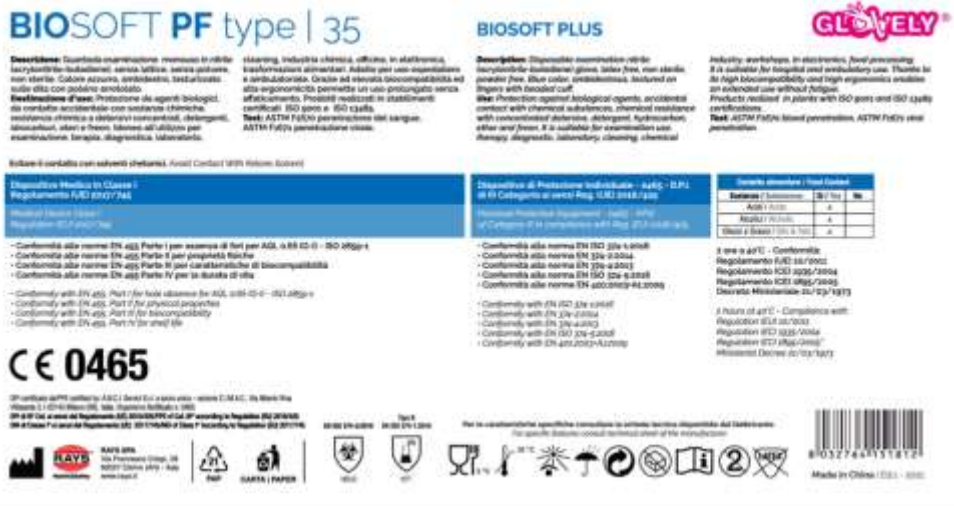
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DESCRIPTION

Non-sterile disposable gloves for examination and exploration in pure acrylic nitrile, with a uniform appearance without imperfections on the entire surface, latex-free, free of internal powder coating (lubricating powder), internally chlorinated to equally ensure ease of donning.

Light blue gloves, interchangeable left and right anatomical shape (ambidextrous) and textured fingers.

Cuffs equipped with an anti-roll elastic band that reinforces the end of the glove, increases its fit and prevents the cuff from rolling up.

Length of the glove such as to allow excellent adherence to the gown in any position of the hand.

BIOSOFT PF TYPE 35 gloves are made in a single body, therefore free of welds, holes and burrs, excellent consistency, elasticity and softness, such as to guarantee perfect adherence and excellent sensitivity and dexterity.

High biocompatibility and ergonomics, which allow prolonged use without fatigue.

Gloves suitable for food contact for different types of food.

Weight: 3.5 g ± 0.3 g (size M).

Average thickness 0.07 mm

(finger thickness 0.10 ± 0.03 mm, palm thickness 0.06 ± 0.03 mm, cuff thickness ≥ 0.05 mm).

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Manufacturer:	RAYS S.p.A. Via Francesco Crispi, 26 60027 Osimo (AN) Italy
Item code:	DAR NI + size
CE marking	<u>Medical Device - class I</u>, pursuant to Regulation (EU) 2017/745 relating to Ministerial Devices. <u>Personal Protective Equipment – category III</u>, pursuant to Regulation (EU) 2016/425 relating to PPEs. Certification issued by A.N.C.I. Services s.r.l. a socio unico – CIMAC. Notified Body no. 0465.
Classificazione CND / EMDN	T01020204
Shelf life	5 years
USE	
Non-invasive medical device of Class I and Personal Protective Equipment of Category III, suitable for the following activities (within the limits of the marked protective levels): hospital and outpatient use for care/ward activities, high-risk interventions for the operator in healthcare field. Suitable for diagnostic, endoscopic and laboratory activities, industrial cleaning, for the chemical industry, workshops, electronics, and food processing.	

RANGE OF AVAILABLE SIZES

SIZE	SIZE COLOUR CODE	ITEM CODE	Basic UDI-DI
XS (5 – 5.5)		DAR NI XS	8032764151799
S (6 – 6.5)		DAR NI S	8032764151805
M (7 – 7.5)		DAR NI M	8032764151812
L (8 – 8.5)		DAR NI L	8032764151829
XL (9 – 9.5)		DAR NI XL	8032764151836

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TECHNICAL FEATURES OF THE DEVICE						
REFERENCE STANDARD	RESULTS					
EN 455-1:2020	DEFECT	INSPECTION LEVEL				AQL
	Micro-holes	G-I sampling procedure according to ISO 2859-1				0.65
EN 455-2:2015 EN 420:2003+A1:2009	SIZE	5 – 5.5 XS	6 – 6.5 S	7 – 7.5 M	8 – 8.5 L	9 – 9.5 XL
	Minimum lenght (mm)	240	250	250	250	250
	Palm width (mm)	≤ 80	80 ±10	95 ±10	110 ±10	≥ 110
	Glove weight (g)	2.5 ± 0.3	3.0 ± 0.2	3.5 ± 0.3	4.0 ± 0.3	4.5 ± 0.3
EN 420:2003+A1:2009 EN ISO 21420:2020	Dexterity		5			
EN 455-2:2015	FORCE AT BREAK		FORCE AT BREAK AFTER AGEING (7 days at 70°C)			
	7.4 N		7.4 N			
EN 455-3:2015	ENDOTOXIN DETERMINATION	POWDER DETERMINATION		DETERMINATION OF EXTRACTABLE PROTEINS		
	< 10 EU/pair	1.60 mg/pcs		41.4 µg/g		
	DETERMINAZIONE DELLE PROTEINE ALLERGENICHE				Unquantifiable	
EN 455-4:2009	DETERMINATION OF THE SHELF LIFE		FORCE AT BREAK			
	5 years		7.3 N			
EN ISO 374-1:2016	Protective gloves of Type B (at least 3 substances) against chemical risks					
EN 374-2:2014	AIR LEAK TESTS		WATER LEAK TESTS			
	Passed		Passed			
EN 16523-1:2015 EN 374-4:2013	CHEMICAL		PERMEATION RESISTANCE EN 16523-1:2015		DEGRADATION RESISTANCE EN 374-4:2013	
	(A) Methanol		0		-	
	(K) Sodium hydroxide at 40%		3		44.2%	
	(P) Hydrogen peroxide at 30%		2		28.8%	
	(T) Formaldehyde at 37%		3		44.9%	
	Chlorhexidine at 4%		6		-	
	Formaldehyde at 4%		6		-	
	Jodopovidone at 10%		6		-	
	Hydrogen peroxide at 3%		4		-	
	Sodium hypochlorite at 10%		6		-	
EN ISO 374-5:2016	PROTECTION AGAINST BACTERIA AND FUNGI			PROTECTION AGAINST VIRUSES		
	Passed			Passed		
EN ISO 10993-5:2009	Tests for in vitro cytotoxicity				Passed	

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EN ISO 10993-10:2013	Skin irritation and sensitization tests		Passed
ISO 16604:2004	Protection from Phi-X174 bacteriophage virus		Passed
ASTM D6319-10	TENSILE STRENGTH	TENSILE STRENGTH AFTER AGING	
	% elongation at break: 507%	% elongation at break: 433%	
ASTM F1670	Resistance to penetration by synthetic blood		Passed
ASTM F1671	Resistance to the penetration of pathogens		Passed
Absence of accelerants	SOSTANZA	LIMITE DI RILEVABILITÀ	RISULTATO
	1,3 benzothiazole	10 mg/Kg	< 10 mg /Kg
	2,3 mercaptobenzothiazole (MBT)	10 mg/Kg	< 10 mg /Kg
	2,2 dithiobis(iobenzothiazole) (MBTS)	10 mg/Kg	< 10 mg /Kg
	Zinc diethyldithiocarbamate	10 mg/Kg	< 10 mg /Kg
	Zinc dimethyldithiocarbamate	10 mg/Kg	< 10 mg /Kg
	2-imidazoline-2-tiol	10 mg/Kg	< 10 mg /Kg
	N-oxydiethylene benzothiazolesulfenamide (MBS)	10 mg/Kg	< 10 mg /Kg
	N-cyclohexyl benzothiazole-2-sulfenamide (CBS)	10 mg/Kg	< 10 mg /Kg
	Tetraethylthiuramdisulfide (TETD)	10 mg/Kg	< 10 mg /Kg
	Tetramethylthiuramdisulphide (TMTD)	10 mg/Kg	< 10 mg /Kg
	Tetraethylthiuramdisulfide (TETD)	10 mg/Kg	< 10 mg /Kg
	Tetramethylthiurammonosulfide (TMDM)	10 mg/Kg	< 10 mg /Kg
Absence of phthalates	Di-isobutyl phthalate (DIBP)	10 mg/Kg	< 10 mg /Kg
	Dibutyl phthalate (DBP)	10 mg/Kg	< 10 mg /Kg
	Dipentyl phthalate (DPP)	10 mg/Kg	< 10 mg /Kg
	Diesyl phthalate (DHP)	10 mg/Kg	< 10 mg /Kg
	Dicyclohexyl phthalate (DCHP)	10 mg/Kg	< 10 mg /Kg
	Di-(2-ethylhexyl) phthalate (DEHP)	10 mg/Kg	< 10 mg /Kg
	Butylbenzyl phthalate (BBP)	10 mg/Kg	< 10 mg /Kg
	Di-isononyl phthalate (DINP)	10 mg/Kg	< 10 mg /Kg

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	FOOD SIMULANT	TEST CONDITIONS		LIMIT	RESULT
		Time	Temperature		
SUITABILITY FOR FOOD CONTACT DM 21/03/1973 Reg. (EU) 10/2011	(A) Ethanol 10% by filling (for foods containing alcohol $\leq 10\%$)	2 hours	40°C	8 mg/dm ²	4.8 mg/dm ²
	(B) 3% acetic acid by filling (for acidic foods pH $\leq 4,5$)	2 hours	40°C	8 mg/dm ²	6.0 mg/dm ²
	(D2) Vegetable oil by filling (for fatty foods)	2 hours	40°C	8 mg/dm ²	< 1 mg/dm ²
ALLERGIC SUBSTANCES	Glove free of latex components (<i>latex free</i>) in the product, in the primary and secondary packaging and in the production process. Low content of potentially allergenic additives. Particularly suitable for personnel sensitive to latex proteins and for use in latex-free departments.				
LUBRICANT SYSTEM	Glove free of internal powder glove (<i>lubricating powder</i>). Internally chlorinated to make the inner surface of the glove smooth, in order to guarantee excellent fit and fit characteristics and allow easy use even with wet hands and minimize the risk of allergic reactions.				

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PACKAGING

PRIMARY PACKAGING (100 pcs)	SECONDARY PACKAGING (1.000 pcs)
Strong cardboard dispenser	Strong cardboard
Single extraction of the glove without the aid of any means	Overlapping storage
Overlapping storage	Impact resistant cardboard
Device classification indication	Dust-proof cardboard
Information on compliance with current regulations	Device classification indication
Information necessary for the recognition of the type of glove, according to the regulations EN 1041:2008+A1:2013 e EN ISO 15223-1: - Commercial name - Item code REF - Size indicated in letters - Name and address of the manufacturer  - Production lot number LOT - Manufacturing date  - Expiry date  - CE marking as MD and as PPE (indicating the initials of the Notified Body) - Pictogram Informative Note  - Pictogram disposable indication ② - Pictogram latex free  - Pictogram EN ISO 374-1 Type B  with tested performance levels - Pictogram EN ISO 374-5  - Pictogram food contact  - Pictogram concerning the disposal of the packaging   - Pictogram storage instructions   	Information necessary for the recognition of the type of glove, according to the regulations EN 1041:2008+A1:2013 e EN ISO 15223-1: - Commercial name - Item code REF - Size indicated in letters - Name and address of the manufacturer  - Production lot number LOT - Manufacturing date  - Expiry date  - CE marking as MD and as PPE (indicating the initials of the Notified Body) - Pictogram Informative Note  - Pictogram disposable indication ② - Pictogram latex free  - Pictogram food contact  - Pictogram concerning the disposal of the packaging   - Pictogram storage instructions   

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INFORMATIVE NOTE

WARNINGS	Before use, check each glove for defects or imperfections. Otherwise, replace the glove. If the gloves are used in contact with chemicals: - make sure that the chemical cannot come into contact with the skin via the cuff; - avoid direct contact of the chemical substance with the skin, even if this substance is declared harmless; - in case of accidental contact with the skin, wash thoroughly with soap and water; - remove and discard the gloves after use. Avoid contact with ketone solvents. The gloves must not be used in applications that require protection against mechanical or thermal risk. Wear gloves with clean, dry hands. Use dry gloves inside.
INSTRUCTIONS FOR USE	Gloves designed for single use. For further information, consult the information printed on the product packaging and in the information note of the manufacturer RAYS S.p.A.
SPECIFIC STORAGE CONDITIONS	Store in a dry place away from light and heat at a temperature <35°C. Keep away from ozone sources or flammable sources. The hygienic conditions of the product are guaranteed only when the package is intact. Keep the packaging for further information and to ensure traceability.
QUALITY CONTROLS	The manufacturer has established and currently maintains a set of procedures to ensure that the product is identified, controlled and tested for compliance with a set of specific requirements.
DISPOSAL	Used gloves may be contaminated with infectious agents or other hazardous materials. Disposal must be carried out in compliance with the national regulations in force. Incineration or landfilling must be carried out under controlled conditions in accordance with applicable national regulations.

MANUFACTURER CERTIFICATIONS

ISO 9001:2015	EN ISO 13485:2016	ISO 14001:2015
Certificate no. 1517.2022 issued by IMQ S.p.a. Notified body no. 0051 Expiry: 29.04.2023	Certificate no. 1514.2022 issued by IMQ S.p.a. Notified body no. 0051 Expiry: 29.04.2023	Certificate no. 0875.2018 issued by IMQ S.p.a. Notified body no. 0051 Expiry: 26.07.2024

RAYS S.p.A.
Products specialist
Safety Division