



EU-TYPE EXAMINATION CERTIFICATE



The following model of Personal Protective Equipment has been subjected to an EU-type examination in accordance with the module B of the PPE regulation (2016/425) and has been shown to satisfy to essential health and safety requirements.

Certificate N° 0075/797/162/05/19/1443

Issued by CTC, Notified Body N°0075, to the following model of personal protective equipment :

Manufacturer : HONEYWELL SAFETY PRODUCTS EUROPE
Immeuble Edison ZI-Paris Nord II 33, Rue des Vanesses 95 958 ROISSY
CDG CEDEX
France

Description

PPE Type : *protective glove against mechanical risks, chemical risks, microorganisms risks, external radioactive contamination risks*

Product reference : CE412W

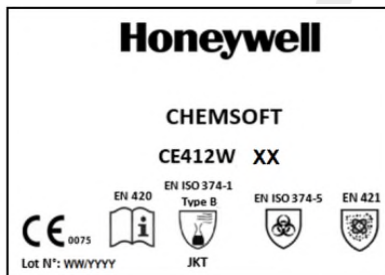
Article code :

Glove description : Nitrile ambidextrous 300mm length disposable glove for clean room.

Texture surface on fingers

Available sizes : 6/XS 7/S 8/M 9/L 10/XL 11/XXL

Pictures :



Address:
HONEYWELL SAFETY PRODUCTS EUROPE
Immeuble Edison ZI-Paris Nord II
33 Rue des Vanesses
95 958 ROISSY CDG CEDEX
France

Address has to be printed on back side of the gloves or on a label inside the gloves.

Reference standard :

Levels of performance / class of protection

EN 420:2003+A1:2009

-

EN ISO 374-5:2016

MICRO-ORGANISMS

EN ISO 374-1:2016

Type B

JKT

EN 421: 2010

Radioactive Contamination

This product is a category III (lethal or irreversible risk). This certificate shall only be used in conjuncture with the conformity assessment procedure according to module C2 (CTC 0075)

At the date of certificate the product is in compliance with Annex XVII of REaCh regulation (n° 1907/2006 and revisions)

Full description of the PPE, reference rules verified in the context of the EU-type examination and information given on the product are detailed in the manufacturer's technical file index 02 dated from October 2019

NOTA : Any modification to new items of the personal protective equipment object of this EU type approval certificate or any modification of the information contained in the manufacturer technical file which served for the deliverance of the EU type approval certificate (change of address, change of company status) should be brought to the attention of the notified body in accordance with Annex V §7.2 of Regulation 2016/425.

Issued in Lyon by
Didier GUISADO
Certification and Quality Manager

Date of first issue : 06 May 2019
End of validity date : 06 May 2024
Update 01: 16 October 2019



Original CTC



In application of the Regulation 2016/425 of the European parliament and the Council of 9th March 2016 related to Personal Protective Equipment and repealing the Directive 89/686/EEC.

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Tél. : +33 (0)4 72 76 10 10 - Fax : +33 (0)4 72 76 10 00 - ctclyon@ctcgroupe.com

Comité Professionnel de Développement Économique (CPDE) Cuir Chaussure Maroquinerie Ganterie
Loi 78-654 du 22.06.1978 - Siret 77564972600160 - Code NAF 9412Z - TVA FR 88775649726

HONEYWELL SAFETY PRODUCTS EUROPE

MANUFACTURER'S TECHNICAL FILE TO THE PPE REGULATION 2016/425

Reference of the product	:	CE412W
Article code	:	
Technical file index	:	02
Last update	:	October 2019

IDENTIFICATION

Reference of the product :	:	CE412W
Article code :	:	
Basic Model		
Technical file index :	:	02
Last update :	:	October 2019

Manufacturer :

HONEYWELL SAFETY PRODUCTS EUROPE

Immeuble Edison ZI-Paris Nord II 33, Rue des Vanesses 95 958 ROISSY CDG
CEDEX

France

tel : 01.49.90.79.79

fax : 01.49.90.79.80

Factory :

Bonric Sdn Bhd

Lot 25A + 26A 44300 Batang Kali Selangor

Malaisie

tel: 360573400

fax: 360574452

GLOVE DESCRIPTION

General glove description :

Nitrile ambidextrous 300mm length disposable glove for clean room. Textured surface on fingers
type of coating finish : no coating

Visual description (picture back and palm sides) :



Field of use

Cleanroom operations, Laboratory, radioactive particle contamination protection

Risk assessment (Essential Health and Safety Requirement. Annex II - PPE Regulation)			
		Applicable	Covered by
§1	Requirements defined in the Annex II §1 are applicable to all PPE	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/> Standard <input checked="" type="checkbox"/> Instruction for use <input checked="" type="checkbox"/> Marking
§1.4	Manufacturer's instructions and information is available	<input checked="" type="checkbox"/>	<input type="checkbox"/> Standard <input checked="" type="checkbox"/> Instruction for use <input type="checkbox"/> Marking
§2.5	PPE which may be caught up during use	<input checked="" type="checkbox"/>	<input type="checkbox"/> Standard <input checked="" type="checkbox"/> Instruction for use <input type="checkbox"/> Marking
§2.12	PPE bearing one or more identification markings or indicators directly or indirectly relating to health and safety	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/> Standard <input checked="" type="checkbox"/> Instruction for use <input checked="" type="checkbox"/> Marking
§2.14	Multi-risk PPE	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/> Standard <input checked="" type="checkbox"/> Instruction for use <input checked="" type="checkbox"/> Marking
§3.9.2.1	Protection against external radioactive contamination	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/> Standard <input checked="" type="checkbox"/> Instruction for use <input checked="" type="checkbox"/> Marking
§3.10.2	PPE intended to protect against substances and mixtures which are hazardous to health and against harmful biological agents - Cutaneous contact	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/> Standard <input checked="" type="checkbox"/> Instruction for use <input checked="" type="checkbox"/> Marking

Available sizes :

Minimum length of glove (mm) Minimum width of glove (mm)	Sizes
300/ 78	6/XS
300/ 178	7/S
305/ 203	8/M
308/ 229	9/L
290/ 254	10/XL
310/ 279	11/XXL

Glove constitution :

	Reference	Color	Material	Surfacic mass	Gauges	Thickness
Palm	2930113	White	Nitrile			0,12mm
Back	2930113	White	Nitrile			0,12mm
Cuff	2930113	White	Nitrile			0,12mm

PROTECTION SCOPE

This glove meets the essential requirements of the Personal Protective Equipment Regulation 2016/425. This glove is designed for against mechanical risks, chemical risks, microorganisms risks, external radioactive contamination risks.

It is a category III product, module C2

Notified Body Reference : CTC (0075)
4 Rue Hermann Frenkel, 69367 Lyon cedex 07- France

GENERAL REQUIREMENTS

Standard EN 420 : 2003 + A1 : 2009

Dexterity : 5

Size : conform

At the date of certificate the product is in compliance with Annex XVII of REACh regulation (n° 1907/2006 and revisions)

SPECIFIC REQUIREMENTS AND PERFORMANCE LEVELS

Chemical hazard EN 374-2 : 2014

Protection offered	Performance levels
Water tightness	conform
Air tightness	conform

Chemical hazard EN ISO 374-1 : 2016

Type :	Type B
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Tested chemical :	CAS N°	Letter	Permeation performance levels:	Degradation value:
n-Heptane	142-82-5	J	3	38.4%
Sodium hydroxide 40%	1310-73-2	K	6	-10.0%
Formaldehyde 37%	50-00-0	T	6	16.6%

Microorganism EN ISO 374-5 : 2016

This glove protect against microorganism
Uncontrolled against viruses

External Radioactif Contamination EN 421 : 2010

This glove protect against external radioactive contamination


TEST REPORTS

Laboratory	CTC	Other
EN 420 + innocuousness	L181122974_1 L181021052_1 L180408031_1 L190917808_1	
EN 374-2	L180306200_1	
EN 16523-1	L160712766_1 L170100319_1 L180101535_1 L160711408_1	
Other	L171223439_1 L180306201_1	

MARKING - PACKAGING

Information printed on the glove :

Logo of Manufacturer :

Logo 

Glove's reference : CE412W

Article Code :

Size indicator

Pictograms related to risks against which protection is offered with performance levels

Information pictogram

Address of Manufacturer :

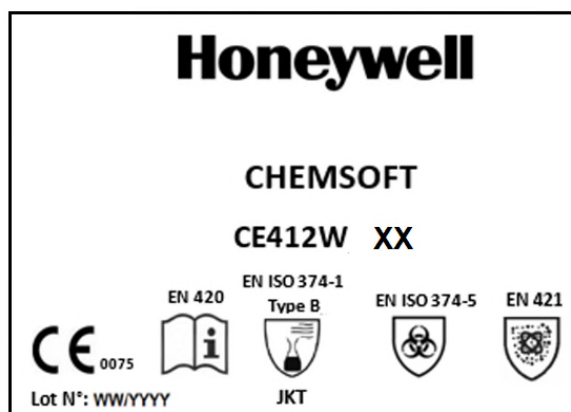
Date of Manufacture (month/year) and/or Serial number :

Marking example :

Address:
HONEYWELL SAFETY PRODUCTS EUROPE
Immeuble Edison ZI-Paris Nord II
33 Rue des Vanesses
95 958 ROISSY CDG CEDEX
France



Address has to be printed on back side of the gloves or on a label inside the gloves.



Method of marking on the glove :

On the outer bag

Packaging :

100 pairs per bag (double bagged), 10 bags per box.

PPE subject to ageing :

The design performance can not be significantly affect by ageing when stored in appropriate conditions (humidity, temperature, clean , ventilated, light).

Declaration of conformity :

Available on : <https://doc.honeywellsafety.com/>

MEANS OF CONTROL

Final inspection plan : in accordance to ISO 2859 level 1
Major defects : NQA = 1,5 / Minor defects : NQA = 10.

Sampling Plan		Quantity of acceptable defects	
Lot Quantity	Sample quantity	Minor Defects	Major Defects
110 to 200	D 8	2	0
201 to 500	F 20	5	1
501 to 1200	G 30	7	1
1201 to 10000	J 80	14	3
10000	K 125	21	5