

EU Declaration of Conformity

Distrubutor:	Stadsing A/S
Distrubutor's Address:	Østre Fælledvej 13, 9400 Nørresundby, DK
Product Brand:	Newton / HandSafe
Product Description:	Nitrile powder free disposable glove
Product Code:	GN90
PPE Category:	Category III
Medical Device Category:	Class I

It is declared that the above product:

- is in conformity with the provisions of Regulation (EU) 2016/425 on personal protective equipment and with National Standards transposing harmonised standards EN ISO 374-1:2016+A1:2018, EN ISO 374-5:2016 and EN 420:2003+A1:2009.

Standard	Performance Levels	
EN ISO 374-1:2016+A1:2018	Type C - K	
EN ISO 374-5:2016	Protection Against Bacteria & Fungi	Protection Against Viruses
	Pass	Pass

- is identical to the personal protective equipment which is the subject of EU Type-Examination Certificate number 2777/11580-05/E00-00, issued by SATRA Technology Europe Limited, Bracetown Business Park, Clonee, Dublin, D15 YN2P, Republic of Ireland (Notified Body number 2777), according to Annex V (Module B) of Regulation (EU) 2016/425.
- is subject to the conformity assessment procedure Module C2 set out in Annex VII of Regulation (EU) 2016/425, under the surveillance of the notified body SATRA Technology Europe Limited, Bracetown Business Park, Clonee, Dublin, D15 YN2P, Republic of Ireland (Notified Body number 2777).
- is in conformity with the provisions of Regulation (EU) 2017/745 on medical devices and with National Standards transposing harmonised standards EN 455-1:2000, EN 455-2:2015, EN 455-3:2015 and EN 455-4:2009, and is self-certified as a Class 1 non-sterile medical device (according to Annex VIII rule 5).
- Stadsing hereby declares that the above-mentioned products are in compliance with the rules of Regulation (EC) 1935/2004 of the European Parliament and of the Council on materials and articles intended to come into contact with food and were manufactured in accordance with the requirements of commission Regulation (EC) No. 2023/2006 relating to manufacturing practice for materials and articles intended to come into contact with food.
- and meet the demands of Comission Regulation (EU) No 10/2011 on materials made of plastic which are intended to come into contact with food as amended.

This EU declaration of conformity is issued under the sole responsibility of the distributor, Stadsing A/S

Place and date of issue: Nørresundby, 14th October 2020

Compliance Information:

Regulation	Standard	Requirement
<u>Medical Device</u> Europe MDR (EU) 2017/745 UK – MDD 93/42/EEC	EN455-1	AQL 1.5
	EN455-2 Length	Minimum 240 mm
	13582 Width S	80 ± 10 mm
	25900 Width M	95 ± 10 mm
	25901 Width L	110 ± 10 mm
	25902 Width XL	≥ 110 mm
	EN455-2 Force at break	≥ 6 N
	EN455-3 Powder level	≤ 2 mg
<u>PPE</u> Europe PPER (EU) 2016/425 UK – PPER (EU) 2016/425 as amended into UK law	EN374-1	Type C
	EN374-5	Tested for virus

Additional Dimensions:

Finger Thickness	0.09 ± 0.02 mm
Palm Thickness	0.07 ± 0.02 mm
Weight per glove	3,5 gram