

## EU Declaration of Conformity

<b>Distrubutor:</b>	Stadsing A/S
<b>Distrubutor's Address:</b>	Østre Fælledvej 13, 9400 Nørresundby, DK
<b>Product Brand:</b>	Newton / HandSafe
<b>Product Description:</b>	Nitrile powder free disposable glove
<b>Product Code:</b>	GN90
<b>PPE Category:</b>	Category III
<b>Medical Device Category:</b>	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, 14<sup>th</sup> October 2020