EC Declaration of Conformity

The manufacturer

STARLAB International GmbH
Neuer Höltigbaum 38
22143 Hamburg
Germany

declares that the powder-free nitrile glove for protection against chemicals and micro-organisms:

STARGUARD SENSITIVE
Catalogue No.: SG-N-XS, SG-N-S, SG-N-M, SG-N-L, SG-N-XL

is manufactured in conformity with Regulation 2016/425 for Personal Protective Equipment (PPE) Category III (complex design) and harmonized standards:

- EN 420: 2003 + A1: 2009
- EN ISO 374-1: 2016 / Type B
- EN 16523-1: 2015
- EN 374-2: 2014 Level 2 (AQL 1.5)
- EN 374-4: 2013
- EN ISO 374-5: 2016
- Protection against Bacteria & Fungi: Pass
- Protection against Viruses: Pass

and is identical to the PPE which is the subject of EC certificate of conformity issued by the notified body SATRA Technology, Wyndham Way, Telford Way, Kettering, Northants, NN16 8SD, UK (Notified Body: 0321) and is subject to the procedure set out in EU type-examination Annex V (Module B) & Annex VII (Module C2) under the supervision of the notified body listed above.

This product is also intended for use as an examination glove and therefore is manufactured in conformity with the provisions of Council Directive 93/42/EEC, in accordance with Annex VII of the EEC Directive, supported by the Conformity Assessment Procedure, adhering to the requirements in accordance with Annex I of the Council Directive 93/42/EEC and the harmonized standards:

- EN455-1:2000
- EN455-2:2015
- EN455-3:2006

for non-invasive medical devices class I according to Annex IX of the Council Directive 93/42/EEC (Rule 1 applied) and for invasive medical devices class I with respect to body orifices intended for transient use according to Annex IX of the Council Directive 93/42/EEC (Rule 5, first section), respectively.

The above mentioned products are also manufactured in conformity with following standards:

- ASTM D6319
- ASTM D6124
- ASTM F1671
- ISO 11193-1
- ISO 21171

Completed: 21 April 2018, Hamburg