



NOTIFIED BODY NB1871

CERTIFICATE OF CONFORMITY OF THE FACTORY PRODUCTION CONTROL

Certificate No.: CE-C-9016-02-23-10-3A

In compliance with Regulation 305/2016/EU of the European Parliament and of the Council of 15th February 2016 (the Construction Products Regulation or CPR), this certificate applies to the construction products.

Medical Gloves + Related products

with intended use described in the Annex

produced by

Abbott Medical Sweden AB

Isafjordsgatan 15, 161 40 Kista, Sweden

and produced in the manufacturing plant

Abbott Medical Sweden AB

Isafjordsgatan 15, 161 40 Kista, Sweden

This certificate attests that all provisions concerning the assessment and verification of constancy of performance described in Annex ZA of the standard(s)

ASTM D6319, Category III, EN 420:2003 + A1:2009, EN 455 1-4, EN ISO 374-1:2016, EN ISO 474-5:2016, CFR 16 CFR 1260, ISO 13485, ISO 10993-10:2002, ISO 9001, FOOD Type: Plactic

under system 2+ and approved and that

the factory production control fulfils all the prescribed requirements set out above.

This certificate will remain valid as long as the test methods and/or factory production control requirements included in the harmonised standard, used to assess the performance of the declared characteristics, do not change, and the product, and the manufacturing conditions in the plant are not modified significantly.

The validity of the certificate is confirmed annually by reissuing while observing the rules for certification.

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