Certificate ES15/93800

The management system of

SGS

ARKA, EUROPE, S.A.

Rua da Ribela 600, 4770-170 Cruz, VN Famalicão, Portugal

has been assessed and certified as meeting the requirements of

ISO 13485:2016 EN ISO 13485:2016

For the following activities

Design, development, manufacture and sale of sterile surgical gloves, non-sterile examination gloves and single-use clothing for hospital and clinical use.

Conceção, desenvolvimento, fabrico e comercialização de luvas cirúrgicas estéreis, luvas de exame não estéreis e produtos de uso único para a área hospitalar e clínica.

This certificate is valid from 30 October 2024 until 16 October 2027 and remains valid subject to satisfactory surveillance audits.

Issue 9. Certified since 16 October 2015

Last certificate expiry date 16 October 2024 Recertification audit date 10 July 2024

C. Moran

Authorised by Liz Moran

Business Manager

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