

Certificate ES15/93800

The management system of

ARKA, EUROPE, S.A.

SGS

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 non-sterile examination gloves and single use clothing for hospital and clinical use.

Distribution of sterile surgical gloves, single-use and non-sterile examination gloves, for hospital and clinical use.

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

Distribuição de luvas cirúrgicas estéreis, luvas de exame não estéreis de uso único, for hospital and clinical use.

This certificate is valid from 29 October 2025 until 16 October 2027 and remains valid subject to satisfactory surveillance audits.

Issue 10. Certified since 16 October 2015

Last certificate expiry date 16 October 2024

Recertification audit date 10 July 2024

L. Moran

Authorised by

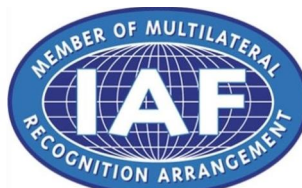
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