Certificate ES15/93800

The management system of

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
Medical devices - Quality management systems - Requirements for regulatory purposes

For the following activities
Design and development, manufacture, and commercialization of non-sterile examination gloves and single-use products for hospital and clinical applications.
Import and distribution of sterile surgical gloves and other non-active, single-use products, both sterile and non-sterile.

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

This certificate is valid from 28 September 2026 until 16 October 2027 and remains valid subject to satisfactory surveillance audits.
Issue 11. Certified since 16 October 2015

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

L. Moran

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UKAS MANAGEMENT SYSTEMS 0005

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