

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Becton Dickinson, S.A.
Ctra. Mequinenza, s/n
Fraga (Huesca)
22520
Spain

Holds Certificate Number:

MD 778144

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

Manufacture of non-active medical devices for injection, infusion, transfusion and dialysis, non-active medical devices for disinfecting, cleaning and rinsing, non-active medical devices with measuring function.

Manufacture of needles, prefilled syringes and components.

The provision of a moist heat sterilization service for internal Becton, Dickinson and Company business units fulfilling applicable quality management system requirements within EN ISO 17665:2006.

The provision of an ethylene oxide sterilization service for internal Becton, Dickinson and Company business units fulfilling applicable quality management system requirements within EN ISO 11135:2014.

For and on behalf of BSI:



Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2023-02-13

Latest Revision Date: 2023-05-03

Effective Date: 2023-05-05

Expiry Date: 2026-05-04

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Certificate No: **MD 778144**

Location	Registered Activities
Becton Dickinson S.A. Ctra. Mequinenza s/n Fraga (Huesca) 22520 Spain	Manufacture of non-active medical devices for injection, infusion, transfusion and dialysis, non-active medical devices for disinfecting, cleaning and rinsing, non-active medical devices with measuring function. Manufacture of needles, prefilled syringes and components. The provision of a moist heat sterilization service for internal Becton, Dickinson and Company business units fulfilling applicable quality management system requirements within EN ISO 17665:2006. The provision of an ethylene oxide sterilization service for internal Becton, Dickinson and Company business units fulfilling applicable quality management system requirements within EN ISO 11135:2014.

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This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.
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