ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

MDSAP
Medical Device Single Audit Program

America

# CERTIFICATE

## No. QS8 040410 0009 Rev. 00

**Certificate Holder:** **B. Braun of Dominican Republic Inc.**
Z. Franca, Ind'l Las Americas
Las Americas, KM #22
Santo Domingo
DOMINICAN REPUBLIC

**Certification Mark:**

**Scope of Certificate:** **Internal Supplier of Production Services for IV Administration Sets, Blood Administration, Piston Syringes and Caps, Gravity Intravascular Administration Sets, Pump Intravascular Administration Sets, IV Sets and Accessories, Infusion Therapy Devices, Needle Free Devices, Filtered Extension Sets, Extensions Sets, Irrigation/Urology Sets and Accessories, Anesthesia IV Devices, Regional Anesthesia and Pain Management Devices, Fluid Transfer Sets and Accessories, Catheter Introducers, Renal Therapy Devices, Pharmaceutical Preparation and Delivery Devices**

**Standard(s):** **ISO 13485:2016**

**Regulatory Authority(ies):** **USA FDA. See attached for listing of specific regulatory requirements.**

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. For details and certificate validity see:
www.tuvsud.com/ps-cert?q=cert:QS8 040410 0009 Rev. 00
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

**REPs Facility ID:** **F008425**
**Report No.:** **721009208**
**Effective Date:** **2025-12-03**
**Expiry Date:** **2028-12-02**


**Date of Issue:** 2025-12-11

( Renee Walker )
Director, US Certification Body, MHS

TÜV®

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

MDSAP
Medical Device Single Audit Program

TÜV SÜD America

# CERTIFICATE

## No. QS8 040410 0009 Rev. 00

**Regulatory Requirements:** **Audit/Certification Criteria**

**United States**
- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807 – Subparts A to D
- 21 CFR Part 820

**Facility(ies):** **B. Braun of Dominican Republic Inc.**
Z. Franca, Ind'l Las Americas, Las Americas, KM #22, Santo Domingo, DOMINICAN REPUBLIC

**Facility Scopes:** Internal Supplier of Production Services for IV Administration Sets, Blood Administration, Piston Syringes and Caps, Gravity Intravascular Administration Sets, Pump Intravascular Administration Sets, IV Sets and Accessories, Infusion Therapy Devices, Needle Free Devices, Filtered Extension Sets, Extensions Sets, Irrigation/Urology Sets and Accessories, Anesthesia IV Devices, Regional Anesthesia and Pain Management Devices, Fluid Transfer Sets and Accessories, Catheter Introducers, Renal Therapy Devices, Pharmaceutical Preparation and Delivery Devices

REPS Facility ID: F008425


**Date of Issue:** 2025-12-11

( Renee Walker )
Director, US Certification Body, MHS

TÜV®

TÜV SÜD America, Inc. • 401 Edgewater Place Suite #500 • Wakefield • MA 01880 • USA • www.tuvsud.com