



America

CERTIFICATE

No. QS6 091507 0006 Rev. 01

Certificate Holder: **Baril Corporation**
50 Ward Hill Avenue
Haverhill MA 01835
USA

Certification Mark:



Scope of Certificate: **Production of Wound Care Dressings for the area of Surgery and Post Operative Recovery**

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

Regulatory Authority(ies): **Brazil ANVISA, 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. Validity of this certificate can be obtained by visiting the website www.tuvsud.com/ps-cert
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

REPs Facility ID: **F002777**

Effective Date: **2021-03-15**

Expiry Date: **2022-03-15**

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Date of Issue: 2021-04-15

(Tina Israel)
Manager, US Certification Body,
Medical and Health Services



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Regulatory Requirements: Audit/Certification Criteria

Brazil

- RDC ANVISA n. 16/2013
- RDC ANVISA n. 23/2012
- RDC ANVISA n. 67/2009

United States

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

Facility(ies):

Baril Corporation
50 Ward Hill Avenue, Haverhill MA 01835, USA

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200 Ward Hill Avenue, Haverhill MA 01835, USA

Facility Scopes:

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50 Ward Hill Avenue, Haverhill MA 01835, USA

Production of Wound Care Dressings for the area
of Surgery and Post Operative Recovery
REPs Facility ID: F002777

Baril Corporation

200 Ward Hill Avenue, Haverhill MA 01835, USA

Shipping and Receiving of Wound Care Dressings
for the area of Surgery and Post Operative Recovery
REPs Facility ID: F002777

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