



America

CERTIFICATE

No. QS6 091507 0006 Rev. 00

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



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 <https://www.tuev-sued.de/product-testing/certificates>

TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

Effective Date: 2019-12-09

Expiry Date: 2022-12-08

Page 1 of 2
Date of Issue: 2019-12-11

(Dawn M. Tibodeau)
Manager, Certification Body MHS

TÜV SÜD America Inc. • 10 Centennial Drive Ste 207 • Peabody, MA 01960 USA • www.tuvsud.com



ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ CERTIFICADO ◆ CERTIFICAT

CERTIFICATE

No. QS6 091507 0006 Rev. 00

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
- 21 CFR Part 820

Facility(ies):

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

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

Facility Scopes:

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

Production of Wound Care Dressings for the area
of Surgery and Post Operative Recovery

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

Page 2 of 2

Date of Issue: 2019-12-11



(Dawn M. Tibodeau)
Manager, Certification Body MHS

TUV SUD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD
ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ CERTIFICADO ◆ CERTIFICAT