

# Certificate of Registration

## QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Solvay Specialty Polymers USA, LLC  
also doing business as  
"Solvay Dental 360,  
Solvay Specialty Polymers USA, LLC"  
4500 McGinnis Ferry Road  
Alpharetta  
Georgia  
30005  
USA

DUNS Number: 09-473-1705

Holds Certificate No:

**MDSAP 675443**

Statement of Conformity: The company listed on this certificate has been audited to and found to conform with the following criteria: ISO 13485:2016 and Australia - Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure; Brasil - RDC ANVISA n. 16/2013, RDC ANVISA n. 23/2012, RDC ANVISA n. 67/2009; Canada - Medical Devices Regulations - Part 1 - SOR 98/282; Japan - MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act; USA - 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

The design, development, manufacture and distribution of denture resins and high performance polymers and polymer based medical devices for dental and medical applications.

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2019-06-03

Effective Date: 2019-06-03

Expiry Date: 2021-12-09



BSI Group America Inc. is an MDSAP authorized auditing organization

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