



SMITHERS
QUALITY ASSESSMENTS

CERTIFICATE OF APPROVAL

This is to Certify that the Quality Management System of:

Molded Products
1112 Chatburn Ave
Harlan, IA 51537

(Page 1 of 2; see Appendix)

has been assessed and approved by Smithers Quality Assessments, Inc., to the following quality management system standards and requirements:

ISO 13485:2016 with Design

The Quality Management System is Applicable to:

The design and manufacturer of molded components and assemblies for medical applications including dialysis.

Approval
Certificate Number: 17.082.1

Original Approval: March 23, 2017

Current Certificate: March 21, 2020

Certificate Expires: March 20, 2023



The use of the accreditation mark indicates accreditation in respect of those activities covered by the above certificate number.


on behalf of SQA - J. Michael Hochschwender, CEO

The approval is subject to the company maintaining its system to the required standards which will be monitored by Smithers Quality Assessments, Inc., 121 S. Main St. Suite 300, Akron, Ohio 44308, USA



APPENDIX A
TO THE CERTIFICATE
OF REGISTRATION NO. 17.082.1



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SMITHERS QUALITY ASSESSMENTS, INC.

Molded Products
1112 Chatburn Ave
Harlan, IA 51537

is certified by Smithers Quality Assessments, Inc. with regard to ISO 13485:2016 with design.

In addition to the address above, the following sites have been assessed and found to be in compliance with the applicable requirements of 13485:2016 with design utilizing a multi-site sampling approach.

Locations:

Molded Products
601 Durant Street / 615 Durant Street
Harlan, IA 51537
Scope: Purchasing, Custom Machining, Secondary Machinery, CNC Machining, Inspection & Testing.

This appendix applies only to those sites listed above. As other sites are assessed and approved, or as sites already approved are removed from active services, this appendix will be amended to show the current status. Sites not listed on this appendix shall not be viewed as approved.

