



**SMITHERS**  
QUALITY ASSESSMENTS

## CERTIFICATE OF APPROVAL

This is to Certify that the Quality Management System of:

**Molded Products**  
1112 Chatburn Avenue  
Harlan, IA 51537

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has been assessed and approved by Smithers Quality Assessments, Inc., to the following quality management system standard 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 systems.

Approval Certificate Number: 17.082.1

Original Approval: March 23, 2017

Current Certificate: March 20, 2023

Certificate Expires: March 19, 2026



*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



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**APPENDIX A**  
TO THE REGISTRATION OF  
REGISTRATION NO.: 17.082.1

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**SMITHERS QUALITY ASSESSMENTS, INC.**

Molded Products  
1112 Chatburn Avenue  
Harlan, IA 51537  
Scope of activities: Design and Manufacturing.

The above site is certified by Smithers Quality Assessments, Inc. with regard to ISO 13485:2016 with design. The following locations are included utilizing a Multi-Site (with No Sampling) approach.

**Location(s):**

Molded Products  
601 Durant Street  
Harlan, IA 51537  
Scope of activities: Purchasing, Custom Machining, secondary machining, inspection & testing

Molded Products  
615 Durant Street  
Harlan, IA 51537  
Scope of activities: Injection molding, inspection & testing

**Applicable Standard: ISO 13485:2016 with Design**

*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.*

