

Quality At All Levels

Phillips-Medisize is committed to providing a robust quality system that supports a variety of requirements. Superior operational performance and full regulatory support ensure risk mitigation, on-time delivery, and flexibility for our customers.

As a quality dedicated contract manufacturer, Phillips-Medisize drives continuous improvement and quality assurance as demonstrated by our Site and System Quality Certifications.

Key Elements of the Phillips-Medisize Quality Management System (QMS)

- Full regulatory compliance
- Qualified processes, underlined by Six Sigma and Lean Management
- Controlled manufacturing environments and standards at all medical facilities
- Full quality management processes from supplier controls through finished product compliant handling
- Additional country-specific implemented standards to meet customers' needs

Regulatory Status	EU Medical Device ISO 13485	Quality System ISO 9001	Medical Device 21 CFR 820	Combo 21 CFR 210/211	Combo 21 CFR 4 compliant	Combo MHRA	Medical Device MHLW
United States Facilities							
Menomonie, WI	X	X	X	X	X	X	X
New Richmond, WI	X	X	X				X
Hudson, WI and Mountain View, CA Design Development Centers	X (with design)	X					
Eau Claire, WI Multi-Shot	X	X					
Phillips, WI	X	X					
Menomonie, WI Metal Injection Molding		X					
Eau Claire, WI Magnesium Injection Molding		X					
European Facilities							
Letterkenny, Ireland	X		X				
Kontiolahhti, Finland	X						
Hillegom, Netherlands	X		X				
Nurensdorf, Switzerland	X	X					
Trhove Sviny, Czech Republic	X		X				