

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization
**Minnesota Rubber & Plastics,
Quadion LLC**
1100 Xenium Lane N
Minneapolis MN 55441
USA

has established and applies a quality management system for medical devices
for the following scope:

(see attachment for scope and sites under certification)

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2019-03-29
Certificate Registration No.: SX 60136392 0001
An audit was performed. Report No.: 31590824 005
This Certificate is valid until: 2021-12-31

Certification Body



Date 2019-03-29



Balazs Bozsik
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TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 1/1, Rev. 0

**Attachment to
Certificate**

Registration No.: SX 60136392 0001
Report No.: 31590824 005

Organization: Minnesota Rubber & Plastics,
Quadion LLC
1100 Xenium Lane N
Minneapolis MN 55441
USA

Scope:

Contract manufacture of custom molded elastomer, over-molded elastomer and thermoplastic parts, related compounds and tooling, controlled environment assembly and packaging for the medical device industry

Additional Sites:

Minnesota Rubber & Plastics, Quadion LLC
45 Precision Drive
Litchfield, MN 55355 USA
Scope: activities related to manufacturing

Minnesota Rubber & Plastics, Quadion LLC
434 Highland Drive
River Falls, WI 54022, USA
Scope: activities related to manufacturing

Certification Body



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Date: 2019-03-29