



Improving Care. Improving Business:

DeRoyal Industries, Inc.

200 DeBusk Lane · Powell, TN 37849 USA +1.888.938.7828 or +1.865.938.7828

October 27, 2022

To Whom It May Concern:

DEROYAL INDUSTRIES, INC., a company incorporated and doing business under the laws of Tennessee, United States of America, hereby attests that:

Industrias Cardiomed S.A.S
Carrera 42N" 54 A 71 Bodega 122
Espacio Sur Itagui
Colombia

Is Authorized, in an Exclusive manner to commercialize, distribute and represent DeRoyal Branded Products in Colombia until April 30, 2027.

Our manufacturing facilities are located in Costa Rica, Guatemala, Dominican Republic, and the United States. The products manufactured in the different locations are designed with the best engineering norms with a high-quality tradition.

Industrias Cardiomed S.A.S, is authorized to obtain sanitary or other registrations, authorizations and certificates regarding all the above-mentioned products in order to acquire the sanitary authorizations needed for the importation and commercialization of such products in Colombia.

Sincerely,

Marcia A. Kilby
Chief Legal Officer

STATE OF TENNESSEE §
COUNTY OF KNOX §

Before me, a Notary Public in and for said State and County, appeared Marcia A Kilby
on this 9 day of November, 2022, and being duly sworn executed this document in my
presence.

9/7/2025



DeRoyal.com



Product Service

Certificate

No. Q6 063838 0019 Rev. 00

Holder of Certificate: **Medax S.r.l. Unipersonale**
Via R. Piva, 1/A
46025 Poggio Rusco (MN)
ITALY

Certification Mark:



Scope of Certificate: **Production and sale of needles, biopsy guns and sets for thoracentesis and paracentesis.**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system (excluding subclause 7.3), which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q6 063838 0019 Rev. 00

Report No.: ITA1925035

Valid from: 2022-10-01

Valid until: 2025-09-30

Date, 2022-09-30

Christoph Dicks
Head of Certification/Notified Body



DAkkS

Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

Product Service

Certificate

No. Q6 063838 0019 Rev. 00

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

Medax S.r.l. Unipersonale
Via R. Piva, 1/A, 46025 Poggio Rusco (MN), ITALY

Production and sale of needles, biopsy guns and sets for
thoracentesis and paracentesis.

Medax S.r.l. Unipersonale
Via Sandro Pertini, 4, 41039 S. Possidonio (MO), ITALY

Production and sale of needles, biopsy guns and sets for
thoracentesis and paracentesis.

Medax S.r.l. Unipersonale
Via sandro pertini 12, 41039 San Possidonio (Mo), ITALY

Warehouse and sales of needles, biopsy guns and sets for
thoracentesis and paracentesis.