

**Business Stream Products  
Certification Department**

**SAO Y BẢN CHÍNH**  
ngày tháng năm



TÜVRheinland®

LGA

Genau. Richtig.

TÜV Rheinland LGA Products GmbH · 90431 Nürnberg

Mr. Fernando Ramon  
Medibu Medical, LLC  
3511 Silverside Road  
WILMINGTON DE 19810  
USA

Contact

Tel. +49 911 655-5225  
Mail [service@de.tuv.com](mailto:service@de.tuv.com)

Date February 26, 2019

**Application for** : QMS  
Certificate No. : SX 60134077 Sheet 0001  
Device : Only for QM-System audit  
Test requirement : EN ISO 13485:2016



*Dương Thanh Huy*  
**GIÁM ĐỐC**

Dear Mr. Ramon,

A surveillance audit what includes also the upgrade to the Version EN ISO 13485:2016 and the new address of the additionally site Miramer FL 33027) of your quality management system was performed.

The audit team confirmed that your quality management system is applied effectively with respect to the above mentioned requirements.

This letter confirms that the above mentioned certification will remain valid and enclosed you receive the revised certificate what replace your current certificate.

Kind regards

Certification body

Roland Gruber

Test sample: no, documentation available

TÜV Rheinland  
LGA Products GmbH

Tillystraße 2  
90431 Nürnberg

Tel. +49 911 655-5225  
Fax +49 911 655-5226  
Mail [service@de.tuv.com](mailto:service@de.tuv.com)  
Web [www.tuv.com/safety](http://www.tuv.com/safety)

Board of Management

Dipl.-Ing.  
Jörg Mähler, Spokesman

Dipl.-Kfm.  
Dr. Jörg Schlösser

Chairman of the  
Supervisory Board

Dipl.-Ing.  
Ralf Scheller

Nuremberg HRB 26013  
VAT No.: DE 811835490

# Certificate

The Certification Body of  
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization  
**Mediblu Medical, LLC**  
**3511 Silverside Road**  
**Wilmington DE 19810**  
**USA**

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

**(see attachment for scope and additional sites)**

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: 2019-02-26  
Certificate Registration No.: SX 60134077 0001  
An audit was performed. Report No.: 31791214 005  
This Certificate is valid until: 2019-12-22

Certification Body



Date 2019-02-26



Roland Gruber

**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**  
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail: cert-validity@de.tuv.com <http://www.tuv.com/safety>

331375  
CỘNG HÒA  
HƯƠNG M  
Y  
MIỀN  
ĐỨC-T

**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

**Attachment to  
Certificate**

**Registration No.:** SX 60134077 0001  
**Report No.:** 31791214 005

**Organization:** Mediblu Medical, LLC  
3511 Silverside Road  
Wilmington DE 19810  
USA

**Scope:** Distribution, Servicing and Final Acceptance Testing of Patient Monitors, Fetal Monitors, Ambulatory Blood Pressure Monitors, Pocket Fetal Dopplers, Pulse Oximeters, Electrocardiographs, Holter Systems, ECG Stress Test Systems, Colposcopes and Video Colposcopes.  
Distribution of Medical Devices.

**Certification Body**



**Date:** 2019-02-26

  
\_\_\_\_\_  
**Roland Gruber**



**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

**Attachment to  
Certificate**

**Registration No.:** SX 60134077 0001  
**Report No.:** 31791214 005



**Organization:** Mediblu Medical, LLC  
3511 Silverside Road  
Wilmington DE 19810  
USA

**Scope:** Additional site:  
2750 SW 145th Ave., Suite 310  
Miramar, FL 33027 USA

Scope:  
Activities related to marketing, sales and administration


Additional site:  
2020 NW 129th Ave., Suite 207  
Miami, FL 33182 USA

Scope:  
Activities related to warehousing, receiving, inspection,  
testing and shipping

**Certification Body**



**Date: 2019-02-26**

  
**Roland Grüber**

