

# EC Certificate

## Full Quality Assurance System Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

Registration No.: HD 2064405-1

Manufacturer: Reach Surgical, Inc.  
120 Xinxing Road, West Zone, TEDA, 300462 Tianjin,  
P.R. China

Products: Circular Staplers with Staples, Linear Staplers with Single Use Loading Units, Procedure Sets for Prolapse and Hemorrhoids, Endoscopic Linear Cutting Staplers, Linear Cutting Staplers with Single Use Loading Units, Single Use Loading Units for Linear Staplers, Single Use Loading Units for Endoscopic Linear Cutting Staplers, Single Use Loading Units for Linear Cutting Staplers, Ultrasound Surgical Equipment, Disposable Ultrasonic Scalpels, Endoscopic Motorized Cutting Staplers, Trocars for Single Use

Replaces Approval, Registration No.: HD 60145655 0001

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II section 4 is required.

Report No.: 190128821 110

Effective date: 2021-05-06

Expiry date: 2024-05-26

Issue date: 2021-05-08

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

TÜV Rheinland LGA Products GmbH • 51105 Köln

Reach Surgical, Inc.  
120 Xinxing Road, West Zone, TEDA, 300462 Tianjin,  
P.R. China

Contact

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Date May 08, 2021

**Application for: Production Quality Assurance**

Certificate No. : HD 2064405-1

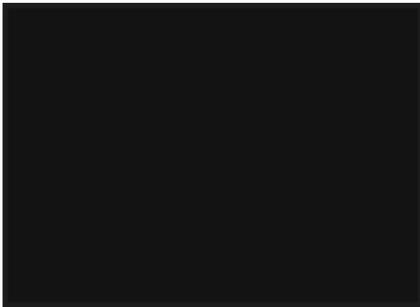
Requirement : MDD Annex II excl. 4

Dear Madam or Sir,

Enclosed please find the new certificate No. HD 2064405-1 replacing the previous certificate.

With effective date of the new certificate, the previous certificate becomes invalid.

Best regards,



TÜV Rheinland  
LGA Products GmbH

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Nuremberg HRB 26013  
VAT No.: DE 811835490

Chairman of the  
Supervisory Board

Dipl.-Ing. Ralf Scheller



## SERTIFIKATAS

### Pilna Kokybės Užtikrinimo Sistema

### Medicinos prietaisų Direktyvos 93/42EEC II Priedas, išskyrus 4 skirsnį

Registracijos Nr: HD 2064405-1

Gamintojas: Reach Surgical

120 Xinxing kelias, WEST Zona, TEDA, 300462 Tianjin,

P.R. Kinija

Produktai: Cirkuliarūs stapleriai su kabutėmis, linijiniai stapleriai, rinkiniai hemorojaus procedūroms, endoskopiniai linijiniai pjovėjai – stapleriai, linijiniai pjovėjai – stapleriai, vienkartinės kabutės endoskopiniams stapleriams, vienkartinės kabutės linijiniams stapleriams, vienkartinės kabutės endoskopiniams pjovėjams-stapleriams, vienkartinės kabutės linijiniams pjovėjams- stapleriams, ultragarsinė chirurginė įranga, vienkartiniai ultragarsiniai skalpeliai, endoskopiniai motorizuoti pjaunantys stapleriai, vienkartiniai trokarai.

Pakeisto patvirtinimo registracijos Nr. HD601456550001

Notifikuotoji įstaiga patvirtina, kad aukščiau minėti produktai atitinka Medicinos prietaisų Direktyvos 93/42EEC II Priedo, išskyrus 4 skirsnį, reikalavimus. Gamintojas yra įsteigęs ir taiko kokybės užtikrinimo sistemą, kuri yra periodinės priežiūros, apibrėžtos direktyvos II Priedo 5 skirsnyje, pagrindas. III klasės medicinos prietaisus patekimą į rinką apibrėžia šis Sertifikatas ir EB pakuotės dizaino Sertifikatas pagal Priedo II skirsnio 4 dalį.

Ataskaitos Nr.: 190128821 110

Galioja nuo: 2021-05-06

Galioja iki: 2024-05-26

Išleidimo data: 2021-05-08

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