

# Certificate of Approval

This is to certify that the Management System of:

## STS Medical Group AD

Industrial Area Sokolovets, 2800 Sandanski, Bulgaria

has been approved by LRQA to the following standards:

### ISO 13485:2016

Approval number(s): ISO 13485 – 00038448

This certificate is valid only in association with the certificate schedule bearing the same number on which the locations applicable to this approval are listed.

The scope of this approval is applicable to:

Manufacture of single-use sterile and non-sterile medical devices:  
Medical clothing, equipment covers, surgical sets, and Customer Procedure Trays; Operation Theatre drapes and drape systems; Urine drainage systems; Wound care products (compresses, pads, gauze bandages);  
Provision of Ethylene Oxide Sterilization for the medical device industry according to the requirements of ISO 11135.



**Paul Graaf**

Area Operations Manager, Europe

Issued by: LRQA Limited



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# Certificate Schedule

Location	Activities
<p><b>Head Office and Production Area</b>                      Industrial Area Sokolovets                      2800 Sandanski                      Bulgaria</p>	<p><b>ISO 13485:2016</b>                      Manufacture of single-use sterile and non-sterile medical devices: Medical clothing, equipment covers, surgical sets, and Customer Procedure Trays; Operation Theatre drapes and drape systems; Urine drainage systems; Wound care products (compresses, pads, gauze bandages); Provision of Ethylene Oxide Sterilization for the medical device industry according to the requirements of ISO 11135.</p>
<p>Industrial Area Borouna                      2800 Sandanski                      Bulgaria</p>	<p><b>ISO 13485:2016</b>                      Manufacture of single-use sterile and non-sterile medical devices: Medical clothing, equipment covers, surgical sets, and Customer Procedure Trays; Operation Theatre drapes and drape systems; Urine drainage systems; Wound care products (compresses, pads, gauze bandages).</p>



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