



# CERTIFICATE



This is to certify that the company

## Essex Industries, Inc.

7700 Gravois  
St. Louis, MO 63123  
United States of America

with the organizational units/sites as listed in the annex

has implemented and maintains a **Quality Management System**.

Scope of certification:  
Design and development of Oxygen Regulators.  
-CND, USA (a,b,c,d)

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of the following standard:

## ISO 13485 : 2016

including applicable country-specific regulatory requirements, as indicated below the scope (full references of abbreviations are listed in the annex)

Certificate registration no.	317218 MDSAP16
Certificate unique ID	170775796
Effective date	2021-07-13
Expiry date	2022-07-12
Frankfurt am Main	2021-07-13



## DQS Medizinprodukte GmbH

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**DQS Medizinprodukte GmbH is recognized under the Medical Devices Single Audit Program.**  
Visit <https://www.mydqs.com/en/customers/customer-database.html> to validate this certificate.



**Annex to certificate**  
**Certificate registration No.: 317218 MDSAP16**  
**Certificate unique ID: 170775796**  
**Effective date: 2021-07-13**



## **Essex Industries, Inc.**

7700 Gravois  
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### **Audited site**

### **DUNS No., site scope and country-specific requirements**

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United States of America

Design and development of Oxygen Regulators.  
**-CND, USA (a,b,c,d)**  
**DUNS No.: 613584481**

**Essex Industries, Inc.**  
4150 Carr Lane Court  
St. Louis, MO 63119  
United States of America

Design and development of Oxygen Regulators.  
**-CND, USA (a,b,c,d)**  
**DUNS No.: 613584481**



**Annex to certificate**  
**Certificate registration No.: 317218 MDSAP16**  
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### **Full references of country-specific requirements of MDSAP participating Regulatory Authorities**

<b>Abbreviation</b>	<b>Jurisdiction</b>	<b>Reference</b>
AUS	Australia	(a) Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 1 – Full Quality Assurance Procedure (b) Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 4 – Production Quality Assurance Procedure
BRA	Brazil	RDC ANVISA n. 16/2013 RDC ANVISA n. 23/2012 RDC ANVISA n. 67/2009
CND	Canada	Medical Device Regulations SOR/98-282, Part 1
JPN	Japan	MHLW Ministerial Ordinance No. 169 (2004) as amended by MHLW Ordinance No. 128 (2014), Articles 4 to 68 Japan PMD Act (as applicable)
USA	United States	(a) 21 CFR Part 803 (b) 21 CFR Part 806 (c) 21 CFR Part 807 (d) 21 CFR Part 820 (e) 21 CFR Part 821