

# Certificate of Registration

## QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that: 3Shape TRIOS A/S  
Holmens Kanal 7  
Copenhagen  
1060  
Denmark

Facility ID Number: F003240

Holds Certificate No: **MDSAP 731241**

The company listed on this certificate has been audited to and found to conform with ISO 13485:2016 including the following country specific requirements:

**Australia:** Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure

**Brazil:** RDC ANVISA n. 67/2009, RDC ANVISA n. 665/2022 - Good Manufacturing Practices, RDC ANVISA n. 551/2021

**Canada:** Medical Devices Regulations - Part 1 - SOR 98/282

**Japan:** MHLW MO No 169 (2004), as amended by MHLW MO No 60 (2021), PMD Act

**USA:** 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

The design, manufacture, distribution and servicing of optical impression systems including associated and standalone software for the areas of dentistry.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2020-06-11

Effective Date: 2023-06-14

Expiry Date: 2026-05-06



BSI Group America Inc. is an MDSAP recognised auditing organization

Certificate No: **MDSAP 731241**

Location

Registered Activities

3Shape TRIOS A/S  
Holmens Kanal 7  
Copenhagen  
1060  
Denmark  
Facility ID Number: F003240

The design, manufacture, distribution and servicing of optical impression systems including associated and standalone software for the areas of dentistry.

3Shape TRIOS A/S  
Niels Juels Gade 9-13  
Copenhagen  
1059  
Denmark  
Facility ID Number: F003240

The design, manufacture, distribution and servicing of optical impression systems including associated and standalone software for the areas of dentistry.



Original Registration Date: 2020-06-11

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This certificate remains the property of BSI and shall be returned immediately upon request.  
An electronic certificate can be authenticated [online](#). Printed copies can be validated at [www.bsigroup.com/ClientDirectory](http://www.bsigroup.com/ClientDirectory)  
To be read in conjunction with the scope above or the attached appendix.

Americas Headquarters: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA  
A Member of the BSI Group of Companies.