

18. May 2018

To whom it may concern

This is to verify, that 3shape A/S has appointed the company;

BSI,
Kitemark Court,
Davy Avenue,
Knowlhill,
Milton Keynes, MK5 8PP,
UK,

as its Notified Body



BSI has in that capacity issued the attached Certificate no. MD 583456, Effective Date: 2018-02-21, Quality Management system – ISO 13485:2016, covering the 3shape site:

3Shape A/S
Holmens Kanal 7
Copenhagen
1060
Denmark

Best regards,



Klaus Rudbæk Høj
Regulatory Affairs Coordinator
3Shape A/S, Holmens Kanal 7, DK-1060 Copenhagen K.

APOSTILLE (Convention de La Haye du 5 octobre 1961)	
1. Country: Land:	Denmark Danmark
This public document Dette offentlige dokument	
2. has been signed by er underskrevet af	Kirsten H. Tiedemann
3. acting in the capacity of i egenskab af	Secretary Sekretær
4. bears the seal/stamp of er forsynet med segl/stempel af	Confederation of Danish Industry Dansk Industri
Certified Attesteret	
5. at i	24 May 2018 24 maj 2018
7. by af	Ministry of Foreign Affairs of Denmark Udenrigsministeriet
8. No nr.	7F6904DE
9. Seal/stamp: Segl/stempel:	
10. Signature: Underskrift:	 Alberte Lyngbo Nielsen



This Apostille only certifies the authenticity of the signature and the capacity of the person who has signed the public document, and, where appropriate, the identity of the seal or stamp which the public document bears. This Apostille does not certify the content of the document for which it was issued.

To verify the issuance of this Apostille, scan the QR code or visit the following website:
<https://ec.europa.eu/eeas/apostille/>

23 MAY 2018

KIRSTEN H. TIEDEMANN



KT *Phan Anh Binh*
Phan Anh Binh
KT *Phan Anh Binh*
Phan Anh Binh
KT *Phan Anh Binh*
Phan Anh Binh

ĐẠI SỨ QUÁN NƯỚC CHXHCN VIỆT NAM TẠI ĐAN MẠCH
EMBASSY OF THE S.R OF VIET NAM IN DENMARK

CHỨNG NHẬN HỢP PHÁP HÓA LÃNH SỰ
CONSULAR AUTHENTICATION

VIỆT NAM
Viet Nam

Giấy tờ, tài liệu này
This public document
has been signed by ALBERTE LYNGBO NIELSEN
Ký

3. với chức danh Thư ký hành chính
acting in the capacity of Administrative Secretary

4. và con dấu của BỘ NGOẠI GIAO ĐAN MẠCH
bears the seal/stamp of the Ministry of Foreign Affairs of Denmark

được chứng nhận/hợp pháp hóa lãnh sự
Certified

5. tại COPENHAGEN 6. ngày 28/05/2018
at Copenhagen 28 May 2018

7. Cơ quan cấp: ĐẠI SỨ QUÁN NƯỚC CHXHCN VIỆT NAM
TẠI ĐAN MẠCH

8. Số: 01.06/HPHLS/18 No: 01.06/HPHLS/18

Embassy of the S.R. of Viet Nam in Denmark



3shape


3shape A/S
Holmens Kanal 7 DK-1060 Copenhagen K
Tel: +45 70 27 85 20 Fax: +45 70 27 26 81
www.3shape.com
CVR-no: 25 55 34 89

Confederation of Danish Industry do hereby certify that the above company is known to us as worthy of confidence.

CONFEDERATION OF DANISH INDUSTRY (DI)
CHAMBER OF INDUSTRY AND COMMERCE SECTION

23 MAY 2018
Kirsten H. Tiedemann
KIRSTEN H. TIEDEMANN



APOSTILLE (Convention de La Haye du 5 octobre 1961)	
1. Country: Land:	Denmark Danmark
This public document Dette offentlige dokument	
2. has been signed by er underskrevet af	Kirsten H. Tiedemann
3. acting in the capacity of i egenskab af	Secretary Sekretær
4. bears the seal/stamp of er forsynet med segl/stempel af	Confederation of Danish Industry Dansk Industri
Certified Attesteret	
5. at i	Copenhagen København
6. the den	24 May 2018 24 maj 2018
7. by af	Ministry of Foreign Affairs of Denmark Udenrigsministeriet
8. No nr.	7F6904DE
9. Seal/stamp: Segl/stempel:	
10. Signature: Underskrift:	<i>Alberte Lyngbo Nielsen</i> Alberte Lyngbo Nielsen



This Apostille only certifies the authenticity of the signature and the capacity of the person who has signed the public document, and, where appropriate, the identity of the seal or stamp which the public document bears. This Apostille does not certify the content of the document for which it was issued.

To verify the issuance of this Apostille, scan the QR code or visit the following website:
<https://ec.europa.eu/eeas/>

bsi.



By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:


3Shape A/S
Holmens Kanal 7
Copenhagen
1060
Denmark

Holds Certificate Number:

MD 583456

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

Design, marketing, and control of manufacture, distribution and service of 3Shape medical scanners with dedicated software solutions and related products.



For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2012-02-21

Latest Revision Date: 2018-02-20

Effective Date: 2018-02-21

Expiry Date: 2021-02-20

Page: 1 of 1




...making excellence a habit.™

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.
An electronic certificate can be authenticated [online](#).
Printed copies can be validated at www.bsigroup.com/ClientDirectory

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A Member of the BSI Group of Companies.

DK0143227

3shape 

3Shape A/S
Holmens Kanal 7, DK-1060 Copenhagen K
Tel: +45 70 27 26 20 Fax: +45 70 27 26 21
www.3shape.com
CVR-no.: 25 55 34 89

