Docusign Envelope ID: 9CD5BE3C-FAFF-4F5D-BCB2-B25E081F684A

Smith & Nephew, Inc.
1450 Brooks Road
Memphis, TN 38116
Tennessee, USA

T: + 1-901-396-2121
T: + 1-800-821-5700 (USA toll free)
www.smith-nephew.com

Smith+Nephew

To Whom It May Concern:

We, Smith & Nephew, Inc., in relation to medical devices we own, would like to explain about the discrepancies in address of the following manufacturing sites.

Manufacturer	Manufacturing site in ISO 13485 certificate	Manufacturing site in CFG	Explanation on the discrepancies
Smith & Nephew, Inc.	1450 Brooks Road, Memphis, Tennessee 38116 USA	1450 Brooks RD. Memphis, TN USA 38116	RD. is the abbreviation for Road and TN is the state abbreviation for Tennessee. Despite the minor differences, the address identifies the same manufacturing facility.
Smith & Nephew Orthopaedics, GmbH	Alemannenstraβe 14, Tuttlingen, D-78532, Germany	Alemannenstrasse 14, Tuttlingen, Baden-Wurttemberg, Germany 78535	Alemannenstraβe is the name in German and in English we use Alemannenstrasse. Baden-Wurttemberg is a state and Tuttlingen is a town in Baden-Wurttemberg. Hence, the CFG provided more information about the state. Despite the minor differences, the address identifies the same manufacturing facility.
Smith & Nephew Orthopedics (Beijing) Co., Ltd	Building #1, No. 98 Kechuang Dong Liu Street, Beijing Economic-Technological Development Area, Beijing 101111, China	No. 98 Kechuang Dong Liu street, Beijing Economic-Technological Development Area, Beijing Beijing, China 101111	The ISO 13485 certificate has provided more information about the building number. Despite the minor difference, the address identifies the same manufacturing facility.
Smith & Nephew Operations Sdn Bhd	PMT 797, Persiaran Cassia Selatan 8, Taman Perindustrian Batu Kawan, Bandar Cassia, Pulau Pinang 14110, Malaysia	PMT 797, Persiaran Cassia Selatan 8 Taman Perindustrian Batu Kawan, Bandar Cassia, Penang, Pulau Pinang Malaysia 14110	The CFG has the additional English word Penang which is the state. Its Malay word is Pulau Pinang which is in both CFG and ISO 13485 certificate. Despite the minor difference, the address identifies the same manufacturing facility.

Docusign Envelope ID: 9CD5BE3C-FAFF-4F5D-BCB2-B25E081F684A

Smith+Nephew

Manufacturer	Manufacturing site in ISO 13485 certificate	Manufacturing site in CFG	Explanation on the discrepancies
Smith & Nephew Orthopedics Ltd	Harrison Way, Leamington Spa, Warwickshire, CV31 3HL, United Kingdom	Aurora House, Spa Park Harrison way, Leamington spa, Warwickshire, United Kingdom CV31 3HL	Aurora House is the name of the building. Spa Park is the general name of the business park the building sits in, which is supplemental information. Despite the minor difference, the address identifies the same manufacturing facility.

We trust that this memorandum clarifies that the minor variations in the physical address locations are negligible and essentially designates the same manufacturer location.

Thank you for your kind attention.

Yours Sincerely,

Signed by:

Lorena Perez

Signer Name: Lorena Perez
Signing Reason: I approve this document
Signing Time: 24-Oct-2024 | 20:10:18 BST

DDDEB1E46D164C5FB7EED275048A5A68

Lorena Perez
Principal Regulatory Affairs Specialist

DocuSign

Certificate Of Completion

Envelope Id: 9CD5BE3CFAFF4F5DBCB2B25E081F684A
Status: Completed
Subject: Complete with Docusign: Letter Address CFG and ISO.docx
Source Envelope:
Document Pages: 2
Signatures: 1
Certificate Pages: 1
Initials: 0
AutoNav: Enabled
EnvelopeId Stamping: Enabled
Time Zone: (UTC) Dublin, Edinburgh, Lisbon, London

Envelope Originator:
Lorena Perez
TJ Smith & Nephew Limited
101 Hessle Road
Hull, Hull HU3 2BN
Lorena.Perez@smith-nephew.com
IP Address: 204.9.32.4

Record Tracking

Status: Original
24-Oct-2024 | 20:07

Holder: Lorena Perez
Lorena.Perez@smith-nephew.com

Location: DocuSign

Signer Events	Signature	Timestamp
Lorena Perez lorena.perez@smith-nephew.com Regulatory Approval Representative 4 Smith & Nephew Security Level: Email, Account Authentication (Required)	Lorena Perez Signature Adoption: Pre-selected Style Signature ID: DDDEB1E4-6D16-4C5F-B7EE-D275048A5A68 Using IP Address: 204.9.32.4 With Signing Authentication via DocuSign password With Signing Reasons (on each tab): I approve this document	Sent: 24-Oct-2024 | 20:09 Viewed: 24-Oct-2024 | 20:09 Signed: 24-Oct-2024 | 20:10

Electronic Record and Signature Disclosure:
Not Offered via DocuSign

In Person Signer Events	Signature	Timestamp

Editor Delivery Events	Status	Timestamp

Agent Delivery Events	Status	Timestamp

Intermediary Delivery Events	Status	Timestamp

Certified Delivery Events	Status	Timestamp

Carbon Copy Events	Status	Timestamp

Witness Events	Signature	Timestamp

Notary Events	Signature	Timestamp

Envelope Summary Events	Status	Timestamps
Envelope Sent	Hashed/Encrypted	24-Oct-2024 | 20:09
Certified Delivered	Security Checked	24-Oct-2024 | 20:09
Signing Complete	Security Checked	24-Oct-2024 | 20:10
Completed	Security Checked	24-Oct-2024 | 20:10

Payment Events	Status	Timestamps

Docusign Envelope ID: 735EA45E-616A-4041-AE24-08C7F9B700F2

Smith & Nephew, Inc.
1450 Brooks Road
Memphis, TN 38116
Tennessee, USA

T: + 1-901-396-2121
T: + 1-800-821-5700 (USA toll free)
www.smith-nephew.com

Smith+Nephew

To Whom It May Concern:

We, Smith & Nephew, Inc., in relation to medical devices we own, would like to explain about the discrepancies in the name and address of the manufacturing sites.

Manufacturing site in ISO 13485 certificate	Manufacturing site in CFG	Explanation on the discrepancies
Smith & Nephew, Inc., Endoscopy Division 76 South Meridian Ave Oklahoma City, Oklahoma 73107-6512, USA	**Smith & Nephew Inc., Endoscopy** 76 S. Meridian Ave. Oklahoma City, OK USA 73107	On the company name, Endoscopy and Endoscopy Division are clarifiers and Smith & Nephew, Inc. is the legal entity. So, the word 'division' is not on the CFG but with or without the word 'division', it still refers to the same company. S. is the abbreviation for South, OK is the state abbreviation for Oklahoma and 6512 is an extension of the zip code. Despite the minor differences, the address identifies the same manufacturing facility.
Smith & Nephew Manufacturing AG Schachenallee 29, 5001 Aarau Switzerland **Smith & Nephew Manufacturing AG** Dammweg 39, 5001 Aarau Switzerland	**Smith & Nephew Orthopaedics AG** Schachenallee 29 Dammweg 39 Aarau, Aargau Switzerland CH-5001	Smith & Nephew Manufacturing AG is listed on the ISO 13485 with production as the scope of the activities. On the CFG, the same site is named as Smith & Nephew Orthopaedics AG, and that is because this is the establishment name, while its business trade name is Smith & Nephew Manufacturing AG, which is the same as that on the ISO 13485 certificate. Please refer to the appendix for the USA FDA Establishment Registration & Device Listing that shows that Smith & Nephew Orthopaedics AG and Smith & Nephew Manufacturing AG are actually the same. As for the addresses, Schachenallee 29 and Dammweg 39 are two different locations, but they are combined and listed under the same heading of Smith & Nephew Orthopaedics AG in the CFG. This is how USA FDA presents information and companies are not able to split it into two addresses on the CFG. As for the word 'Aargau' in the CFG, Switzerland is divided into several territories and Aargau is one of the

Docusign Envelope ID: 735EA45E-616A-4041-AE24-08C7F9B700F2

Smith+Nephew

Manufacturing site in ISO 13485 certificate	Manufacturing site in CFG	Explanation on the discrepancies
		territories (Canton). Aarau is a district/ town in Aargau. Hence, the CFG provided more information about the territory name. As for the word 'CH-5001', CH is the country code for Switzerland. Despite the minor differences, all addresses identify the same manufacturing facilities.

We trust that this memorandum clarifies that the minor variations in the manufacturing site names, and physical address locations are negligible and essentially designates the same manufacturer location.

For applications submit to Vietnam Ministry of Health, the full information as below will be submitted in our applications:

1. **Smith & Nephew, Inc., Endoscopy Division**
   76 South Meridian Ave
   Oklahoma City, Oklahoma
   73107-6512, USA

2. **Smith & Nephew Manufacturing AG (Or "Smith & Nephew Orthopedics AG")**
   Schachenallee 29, 5001 Aarau, Switzerland

3. **Smith & Nephew Manufacturing AG (Or "Smith & Nephew Orthopedics AG")**
   Dammweg 39, 5001 Aarau, Switzerland

Thank you for your kind attention.

Yours Sincerely,

Signed by:
Lorena Perez
Signer Name: Lorena Perez
Signing Reason: I approve this document
Signing Time: 24-Oct-2024 | 20:13:22 BST
DDDEB1E46D164C5FB7EED275048A5A68

Lorena Perez
Principal Regulatory Affairs Specialist

DocuSign

Certificate Of Completion

Envelope Id: 735EA45E616A4041AE2408C7F9B700F2
Subject: Complete with Docusign: Letter Different Name.docx
Source Envelope:
Document Pages: 4
Certificate Pages: 1
AutoNav: Enabled
EnvelopeId Stamping: Enabled
Time Zone: (UTC) Dublin, Edinburgh, Lisbon, London

Signatures: 1
Initials: 0

Status: Completed

Envelope Originator:
Lorena Perez
TJ Smith & Nephew Limited
101 Hessle Road
Hull, Hull HU3 2BN
Lorena.Perez@smith-nephew.com
IP Address: 204.9.32.4

Record Tracking

Status: Original
24-Oct-2024 | 20:11

Holder: Lorena Perez
Lorena.Perez@smith-nephew.com

Location: DocuSign

Signer Events	Signature	Timestamp
Lorena Perez lorena.perez@smith-nephew.com Regulatory Approval Representative 4 Smith & Nephew Security Level: Email, Account Authentication (Required), Login with SSO	Lorena Perez Signature Adoption: Pre-selected Style Signature ID: DDDEB1E4-6D16-4C5F-B7EE-D275048A5A68 Using IP Address: 204.9.32.4 With Signing Authentication via DocuSign password With Signing Reasons (on each tab): I approve this document	Sent: 24-Oct-2024 | 20:12 Viewed: 24-Oct-2024 | 20:12 Signed: 24-Oct-2024 | 20:13

Electronic Record and Signature Disclosure:
Not Offered via DocuSign

In Person Signer Events	Signature	Timestamp

Editor Delivery Events	Status	Timestamp

Agent Delivery Events	Status	Timestamp

Intermediary Delivery Events	Status	Timestamp

Certified Delivery Events	Status	Timestamp

Carbon Copy Events	Status	Timestamp

Witness Events	Signature	Timestamp

Notary Events	Signature	Timestamp

Envelope Summary Events	Status	Timestamps
Envelope Sent	Hashed/Encrypted	24-Oct-2024 | 20:12
Certified Delivered	Security Checked	24-Oct-2024 | 20:12
Signing Complete	Security Checked	24-Oct-2024 | 20:13
Completed	Security Checked	24-Oct-2024 | 20:13

Payment Events	Status	Timestamps

FDA

FDA Home[3] Medical Devices[4] Databases[5]

Establishment Registration & Device Listing

New Search Back To Search Results

Establishment:
SMITH & NEPHEW ORTHOPAEDICS AG
Business Trade Name:
SMITH & NEPHEW MANUFACTURING AG

SCHACHENALLEE 29
DAMMWEG 39
AARAU Aargau, CH CH-5001
Registration Number: 9613369
FEI Number*: 3002807893
Status: Active
Date Of Registration Status: 2025

Owner/Operator:
Smith & Nephew, Inc.[6]
7135 Goodlett Farms Parkway
Cordova, TN US 38016
Owner/Operator Number: 1020279[7]

Official Correspondent:
Beth Zis
150 Minuteman Road
Andover, MA 01810
Phone: 1-978-7491260

US Agent:
Jason Sells
Smith & Nephew Inc.
7135 Goodlett Farms Pkwy
Cordova, TN US 38016
Phone: 901 3995520 Ext
Email: Jason.Sells@Smith-Nephew.Com

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

Links on this page:

1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
2. http://www.addthis.com/bookmark.php
3. https://www.fda.gov/
4. https://www.fda.gov/Medical-Devices
5. https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases
6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=1020279&OwnerOperator
7. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=1020279&OwnerOperator

Page Last Updated: 10/21/2024

Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.
Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | العربية | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsc | 日本語 | فارسی | English

Accessibility Contact FDA Careers FDA Basics FOIA No FEAR Act Nondiscrimination Website Policies / Privacy

FDA

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

USA.gov

For Government For Press

Combination Products Advisory Committees Science & Research Regulatory Information Safety Emergency Preparedness International Programs News & Events Training and Continuing Education Inspections/Compliance State & Local Officials Consumers Industry Health Professionals FDA Archive Vulnerability Disclosure Policy

U.S. Department of Health & Human Services

Links on this page:

1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
2. http://www.addthis.com/bookmark.php
3. https://www.fda.gov/

4. https://www.fda.gov/Medical-Devices
5. https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases
6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=1020279&OwnerOperator
7. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=1020279&OwnerOperator