implantcast GmbH · Lüneburger Schanze 26 · 21614 Buxtehude

implantcast GmbH
Lüneburger Schanze 26
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E-Mail: info@implantcast.de
Internet: www.implantcast.de

To: **INVIMA**

To whom it may concern

Country: Colombia

Buxtehude, 29.08.2023

Letter of authorisation

Herewith we authorise the company:

E.D.M. – EQUIPOS & DISPOSITIVOS MEDICOS
SAS – Medical Devices & Equipment
Calle 106 N. 57-20
Puente Largo
11111 Bogotá
Colombia

to perform registration, renewal of existing marketing authorisations and registrations as well as all other regulatory activities of our products. As our sole and exclusive distributor in the Territory of Colombia, E.D.M. – EQUIPOS & DISPOSITIVOS MEDICOS is authorised to sell and distribute our products and participate in official tenders.
Our products are orthopaedic implants as well as medical instruments. All implants are manufactured in Germany by us in accordance with the European Medical Device Directive (93/42/EEC) as well as the European Medical Device Regulation (EU 2017/745) and the German law for medical implants (MPDG).

This authorisation is valid for 5 years.

Kind regards,

implantcast

Jens Saß
CEO / managing director

Bankverbindung:
Sparkasse Harburg-Buxtehude
IBAN DE51 2075 0000 0050 0448 66
SWIFT-BIC NOLADE21HAM

Handelsregister: HRB 120629, Tostedt
Geschäftsführer: Jens Saß
Erfüllungsort und Gerichtsstand Buxtehude
USt. ID Nr. DE 1164 639 57

MED CERT
EN ISO 13485

Agosto 31 de 2018

Para: **INVIMA República de Colombia**

Referencia: **CARTA DE AUTORIZACION**

Nosotros **Synimed**, empresa legalmente constituida bajo las leyes de la República Francesa, con domicilio en Z.A. de L'Angle – 19370 Chamberet – France, por medio de la presente certificamos que:

EDM EQUIPOS Y DISPOSITIVOS MEDICOS SAS

Identifcada con NIT N° 900.399.132-1, y con oficinas principales localizadas en la Calle 106 # 57 20, Puente Largo, Bogotá, Colombia, legalmente representada por Germán Forero Reyes, identificado con cédula de ciudadanía # 19.381.624 de Bogotá, está autorizada a importar y distribuir en Colombia los productos manufacturados por Synimed.

EDM EQUIPOS Y DISPOSITIVOS MEDICOS SAS también está autorizada para registrar y / o modificar Registros Sanitarios de los productos de **Synimed,** ante las autoridades de Salud Colombianas en nombre de **Synimed.**

SYNIMED
Synergie Ingénierie Médicale
Zone Artisanale de l'Angle
19370 CHAMBERET
Tél. : 05 55 98 31 38 Fax : 05 55 98 35 76
SIRET : 438 089 971 00024 - Code APE 3250 A

Carlos Paez
Manager

SBM
Science & Bio Materials

INVIMA
To whom it may concern
Country: COLOMBIA

Lourdes, March 3rd, 2022

Letter of authorization

We, **S.B.M. SAS, Science & Bio Materials**, a legally constituted company under the laws of France with main headquarters located at Zone Industrielle du Monge, 65100 Lourdes, FRANCE.

Herewith confirm that we have authorized the company:

E.D.M. EQUIPOS Y DISPOSITIVOS MEDICOS SAS, legally represented by Germán Forero-Reyes, Id # 19.381.624 , with its main headquarters located at CALLE 106 57 20,Puente Largo Zip Code 11111, Bogota Colombia, as a distributor of our S.B.M.'s products manufactured by S.B.M S.A.S Science & Bio Materials:

Family of implants for High Tibial Osteotomy, Femoral Osteotomy, ACL repair, Implants for osseous filling, Implants for Rotator Cuff repair, Meniscus repair in the territory of COLOMBIA. E.D.M is allowed to import and distribute these products.

Furthermore, we authorize E.D.M to request and modify registration of the whole range of our S.B.M.'s products: Family of implants for High Tibial Osteotomy (Otis-C-Plus®, Otis F®, OTIS® self-tapping locking screw and Otis® Implant), Femoral Osteotomy (Otis-F®), ACL repair (Ligafix® 30, Ligafix® 60, Pullup®, Pullup® XL, Pullup® BTB, Pullup® XL BTB, Btloop®, Btloop® XL, Pullup® Tex Clip) Implants for osseous filling (Bio 1®), Implants for Rotator Cuff repair (Fixit®, Fixit® Knotless and Powertape®), Meniscus repair (MENIX® and MENIX® DUO) on behalf of S.B.M. SAS Science & Bio Materials, with the INVIMA.

E.D.M shall be the titular of the registration of the families of references of S.B.M.'s products before the INVIMA.

Our products are orthopedic implants as well as medical instruments. All products are manufactured by our company in France based on the European Medical Device Directive (93/42/EEC) and the MDR (European Medical Devices Regulation) regarding the production of medical implants.

This authorization is based on the distributorship agreement and is valid for 5 years.

Kind regards,

S.B.M
ZI du Monge
65100 LOURDES - FRANCE
Tél. 05 62 42 21 01 - Fax 05 62 42 21 00

Mr. Denis CLEMENT
CEO
S.B.M. SAS, Science & Bio Materials