SGS

The management system of

Techfit Digital Surgery, Inc.

1511 Aviation Centre Pkwy, Suite 220H Daytona Beach, FL 32114, United States

has been assessed and certified as meeting the requirements of

ISO 13485:2016 EN ISO 13485:2016

For the following activities:

Design, development, production of patient-specific reconstruction implants, 3D printed surgical guides, 3D printed anatomical models, and contract manufacturing of bone fixation systems for medical device companies

This certificate is valid from 18 June 2021 until 18 June 2024 and remains valid subject to satisfactory surveillance audits.

Recertification audit due a minimum of 60 days before the expiration date.

Issue 1. Certified since 18 June 2021.

This is a multi-site certification.

Additional site details are listed on the subsequent page.

Authorised by



SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t+44 (0)151 350-6666 f+44 (0)151 350-6600 www.sqs.com

21HC 13485 2016 0421 M2

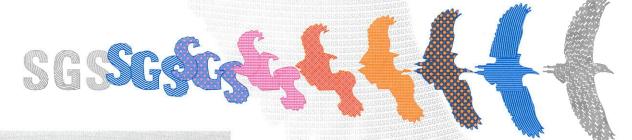
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Techfit Digital Surgery, Inc

ISO 13485:2016 EN ISO 13485:2016



Issue 1

Additional facilities:

Cra 47# 100 sur 40 Bodega 14, Centro Ind. Portal del Sur. , La Estrella, Antioquia , Colombia

Scope: Design, development, production of patient-specific reconstruction implants, 3D printed surgical guides, 3D printed anatomical models.





