Sculpteo Press Release

The 3D printing company Sculpteo obtains ISO 13485 certification for the manufacturing of medical devices

3D printing leader Sculpteo reaches a major milestone in quality and safety for medical device production, obtaining ISO 13485 certification for medical product manufacturing

Villejuif, France xx/05/2024 - Sculpteo, the leader in 3D printing, announces that it has been awarded the ISO 13485 certification by the "Association Française de Normalisation" (AFNOR) for its technology and excellence in medical device manufacturing. This certification covers a wide range of medical products. Sculpteo is stepping up its presence in the healthcare sector, in line with the industry's strictest standards, with customized products that are easier to wear and more compatible with the patient's body, made to order or in series.

ISO 13485, a guarantee of excellence

ISO 13485 defines the requirements for a quality control system applied to medical devices. It imposes strict criteria established by the certifying body, ensuring full traceability of all

operations and control of changes in manufacturing processes. There are different classes of medical devices, each associated with a specific level of risk, ranging from Class I to Class III.

Sculpteo's certification scope covers classes I and IIa:

– Class I (lowest risk class), including, but not limited to prosthesis covers, corrective eyeglasses, vehicles for disabled people, crutches, etc. ;

– Class IIa (moderate/measured risk potential), including, but not limited to, certain prosthesis fittings, contact lenses, ultrasound equipment, dental crowns;

– Class IIb (high/important risk potential), including condoms and contacts disinfectants,

– Class III (highest risk class) , which includes, for example, breast implants, stents, hip prostheses, etc.

Sculpteo's commitment to innovation and quality

With Class I and IIa products, Sculpteo is positioning itself as an expert in the manufacture of prostheses, orthoses and plagiocephaly helmets - innovative, high-quality solutions that meet the specific needs of its customers and their patients.

Qwadra testimonial: "*At Qwadra, we are delighted to celebrate our partner Sculpteo's achievement of the prestigious ISO 13485 certification. This achievement strengthens our mutual trust and solidifies our partnership. Through this qualification, we are convinced that we can offer our customers orthopedic devices of impeccable quality, guaranteeing their well-being and satisfaction.*" (Luc Boronat, CEO of Qwadra)

For Alexandre d'Orsetti CEO Sculpteo, "*This new certification confirms the role of Sculpteo and 3D printing in industrial manufacturing, this time in the highly demanding world of medical devices. Together with our partners, we can now envision manufacturing healthcare devices that are more comfortable, effective and aesthetically pleasing.*"

How does it work?

1. Identification of appropriate materials for each application.
2. Selection of materials to ensure durability, biocompatibility and regulatory compliance.
3. Rigorous testing to validate material and device compliance with industry standards.
4. Maintain complete documentation throughout the project, including design records, material batch numbers and manufacturing specifications.
5. Sculpteo defines its own specifications for medical devices, and adapts to specific customer requirements on request.
6. Production of Class I and IIa medical devices.

A significant step forward

This ISO 13485 certification marks a significant step forward in Sculpteo's commitment to innovation, quality and the safety of medical products.

About Sculpteo

Sculpteo, a pioneer and specialist in digital manufacturing, offers an online 3D printing service. Sculpteo provides an online platform to securely upload 3D files and select from 75+ materials and finishing options. Professional engineers and technicians produce parts on industrial 3D printing technologies before sending them to businesses and individuals worldwide. Based in Paris and San Francisco, Sculpteo offers on-demand 3D printing and manufacturing at a large scale for start-ups, SMEs, and design studios. Sculpteo offers its professional 3D printing service alongside its expert Design Studio to help businesses integrate additive manufacturing into their product development and production systems. Sculpteo was created in 2009 by Eric Carreel and Clément Moreau and is led by Alexandre d'Orsetti, former director of Sculpteo's design studio. BASF New Business GmbH acquired it in November 2019.

For more information: www.sculpteo.com

About BASF 3D Printing Solutions

BASF 3D Printing Solutions GmbH, headquartered in Heidelberg, Germany, is a 100% subsidiary of BASF New Business GmbH. It focuses on establishing and expanding the business under the Forward AM brand with advanced materials, system solutions, components, and services in the field of 3D printing. BASF 3D Printing Solutions is organized into startup-like structures to serve customers in the dynamic 3D printing market. It cooperates closely with the global research platforms and application

technologies of various departments at BASF and research institutes, universities, startups, and industrial partners. Potential customers are primarily companies that intend to use 3D printing for industrial manufacturing. Typical industries include automotive, aerospace, and consumer goods.

For more information, please visit: www.forward-am.com

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