



## Certificate of Registration

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

This is to certify that: Stem Alpha SA

60 Route de Saint Bonnet

SAINT LAURENT DE CHAMOUSSET

69930 France

Holds Certificate Number:

MD 616902

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

Design, development, control of manufacture and sales of sterile solutions for preservation of corneas prior to potential transplant.

Conception, développement, contrôle de fabrication et commercialisation de solutions stériles pour la préservation de cornées potentiellement destinées à la transplantation.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2015-09-09

Latest Revision Date: 2021-09-06

Effective Date: 2021-09-09 Expiry Date: 2024-09-08

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...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 <u>online</u>. Printed copies can be validated at www.bsigroup.com/ClientDirectory