

Certificate of Registration

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

This is to certify that:

DSM Biomedical B.V.
Urmonderbaan 22
Geleen
6167 RD
The Netherlands

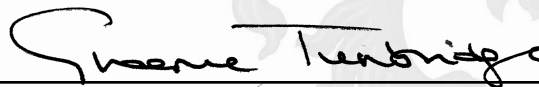
Holds Certificate Number:

MD 563485

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, and manufacturing of biomaterials: coating formulations, derivatives of polyethylene material, and polymers for controlled release applications. Acting as an EU Authorized Representative for affiliated medical device manufacturers located outside the European Union.

For and on behalf of BSI:



Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2010-07-01

Latest Revision Date: 2026-04-27

Effective Date: 2026-08-02

Expiry Date: 2029-08-01

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