

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No.**CE 707605****Issued To:**

**NovaCutis GmbH
Konrad-Adenauer Allee 1-11
Bad Vibel
61118
Germany**

In respect of:

The design, manufacture and distribution of sterile absorbable hyaluronic acid dermal filler implants and associated delivery system intended for treatment of HIV-induced facial lipoatrophy, to restore volume loss in facial subcutaneous adipose tissue, and/or correction of contour and anatomic deformities.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2021-05-20**

Date: **2021-05-20**

Expiry Date: **2024-05-26**

...making excellence a habit.™

Page 1 of 2

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 707605

Issued To:

NovaCutis GmbH
Konrad-Adenauer Allee 1-11
Bad Vöbel
61118
Germany

Number	Device Name	Intended purpose per IFU
Class III		
SMD0204	Absorbable Hyaluronic Acid Dermal Fillers	See CE 711684

First Issued: **2021-05-20**Date: **2021-05-20**Expiry Date: **2024-05-26**

...making excellence a habit.™

Page 2 of 2

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

EC Certificate - Full Quality Assurance System

Certificate History

Certificate No: **CE 707605**
Date: **2021-05-20**
Issued To: **NovaCutis GmbH**
Konrad-Adenauer Allee 1-11
Bad Vibel
61118
Germany

Date	Reference Number	Action
20 May 2021	3387558	First issue.
Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3		
11 February 2022	3483289	Change of Legal Manufacturer address to NovaCutis GmbH: Friedrich-Ebert-Anlage 36, 60325 Frankfurt, Germany.

...making excellence a habit.™

Page 1 of 1

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

11 February 2022

NovaCutis GmbH
Friedrich-Ebert-Anlage 36
Frankfurt
60325
Germany

To whom it may concern,

The transitional provisions specified in MDR Article 120(3) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26th May 2021.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under MDR Article 120(3) and as per the guidance provided in MDCG 2020-3. The related MDD certificate specified below remains valid until the expiry date specified on the certificate.

Certificate	Directive and Annex	Reference Number	Changes approved
CE 707605	93/42/EEC Annex II excluding Section 4	3483289	Change of Legal Manufacturer address to NovaCutis GmbH: Friedrich-Ebert-Anlage 36, 60325 Frankfurt, Germany.

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,



Gary Slack
Senior Vice President, Medical Devices