ezú electrotechnical testing institute

Authorized Body No. 201
Notified Body No. 1014
Accredited Testing and Calibration Laboratory
Accredited Certification and Inspection Body

Elektrotechnický zkušební ústav, s. p., Pod lisem 129/2, Troja, 182 00 Prague 8

Aesthetic Group
ZA de la Gobette
60540 Puiseux le Hauberger
France

12. 09. 2023, Prague

Extended transition period confirmation letter

To whom it may concern,

Confirmation of the status of the extended transition period for legacy devices CE marked under Directive 93/42/EEC (MDD) in the framework of Regulation (EU) 2023/607 amending Regulation (EU) 2017/745 (MDR)

This letter confirms that the extended transition period is also applicable to below mentioned certificates issued by Elektrotechnický zkušební ústav, s. p. as a Notified Body no. 1014 under Directive 93/42/EEC:

Certificate identification	Date of issue	Date of validity
MED 180073	18. 12. 2018	17. 12. 2023

Regardless of the date of validity all these certificates remain valid till 26. 05. 2024.

All medical devices covered by these certificates can be CE marked and placed on the EU marked till 26. 05. 2024.

On behalf of the Notified Body,

Mgr. Miroslav Sedláček
Head of Certification Body

Elektrotechnický zkušební ústav, s. p.
Pod lisem 129/2
182 00 Prague 8
Czech Republic

Komerční banka, Prague 8
IBAN: CZ49 0100 0001 2328 8581 0287
SWIFT: KOMBCZPP
Bank account: No. 1806081/0100

phone: +420 266 104 111
e-mail: info@ezu.cz
www.ezu.cz

ZA La Gobette
60540 Puiseux le Hauberger (F)
Tel : (33) 03 44 72 39 79
Fax : (33) 03 44 74 18 94
E-mail : info@aestheticgroup.fr
www.aestheticgroup.fr

Date: 08/11/2023

1- We declare that the devices covered by CE certificate no. MED 180073 still comply with directive 90/385/EEC or directive 93/42/EEC

2- We declare that there is no significant change in the design and intended use of the relevant device or devices,

3- We declare that the relevant devices do not pose an unacceptable risk to the health or safety of patients, users or other persons or to other aspects of the protection of public health,

4- We declare that we will implement a quality management system (QMS) in accordance with Article 10(9) of the MDR no later than May 26, 2024,

5- We declare that Aesthetic Group has made a formal application to a notified body in accordance with the first subparagraph of Article 4.3 of Annex VII of the MDR for conformity assessment for the devices in question (see "*MDR confirmation Letter_Aesthetic group")*

6- Not later than 26 September 2024, a statement that a written agreement has been signed between the relevant notified body and the manufacturer in accordance with the second subparagraph of Article 4.3 of Annex VII of the MDR.

Catherine DALLA RIVA

Ing. Regulatory Affairs

Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*[1]
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	AESTHETIC GROUP
Manufacturer address and contact details	ZA La Gobette 60540 Puiseux le Hauberger (F)
Single Registration Number (SRN) (if available)	FR-MF-000000347

Authorised Representative name (if applicable)	N/A
Authorised Representative address and contact details	N/A
Single Registration Number (SRN) (if available)	N/A

Notified body name (if applicable)	E.Z.U □ See attached schedule
Notified body number (if applicable)	1014 □ See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	CE certificate no. MED 180073 □ See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	17.12.23 □ See attached schedule

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

End date of extended validity/transition period	26/09/2024 □ See attached schedule

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*[2]
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

  Choose applicable statements:

  ☐ Expired *before* 20 March 2023:

  ☐ Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of a device(s) intended to substitute that/those device(s), or

  ☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request), or

  ☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

  Choose one of the following statements only if a derogation per Article 59(1) or a requirement per Article 97(1) has been granted by a Competent Authority:

  ☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

  ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

[2] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

☒Expired/expires *after* 20 March 2023:

Choose one applicable statement:

☒Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

- **Upclassified devices**

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

Choose one applicable statement:

☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitutes and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

- **Quality Management System (QMS)**

Choose one applicable statement:

☐ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.

☒A QMS in accordance with Article 10(9) MDR is in place.

☐ A notified body has issued the attached certificate for the MDR-compliant QMS.

- **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

AESTHETIC GROUP

PUISEUX LE HAUBEGER 10-01-24

DALLA RIVA Catherine – Regulatory Affairs Ing. -

Quality@aestheticgroup.fr

AESTHETIC GROUP

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
LIPOTRANSFER CANNULAS	MED 180073	17.12.2023	EZU 1014	DNV 2460	26.09.24	N/A
LIPOSUCTION CANNULAS	MED 180073	17.12.2023	EZU 1014	DNV 2460	26.09.24	N/A
FILLING MICRO-CANNULAS	MED 180073	17.12.2023	EZU 1014	DNV 2460	26.09.24	N/A
CANNULA + NEEDLE KIT	MED 180073	17.12.2023	EZU 1014	DNV 2460	26.09.24	N/A

[3] for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

Aesthetic Group
Address: Za de la Gobette,
Puiseux le Hauberger,
60540, Oise
France

DNV Business Assurance Czech Republic s.r.o.
Thákurova 4
160 00 Prague
Czech Republic
Tel: +420 233 321 231
IČO: 02485818

Date:	Our reference:	Your reference:
7.11.2023	PRJN-343354	

Subject: Request for the confirmation of Medical Devices Regulation certification status

This is to confirm that the company Aesthetic Group, based in Oise, France signed the contract with DNV Product Assurance AS, for Medical Devices Regulation 2017/745/EU on 26th January, 2022.

Certification assessments and audits in the following scope: **Design, production, and final product inspection/testing of Single use medical devices as lipotransfer cannulas, liposuction cannulas and micro cannulas.**

Certificate number: C519284

Do not hesitate to contact our office in case of any questions.

Ing. Mária Lichnerová

Country Manager, DNV Product Assurance AS