EC CERTIFICATE

FULL QUALITY ASSURANCE SYSTEM CERTIFICATE

Cert no. C000941LVFS

issued to

Ilexis AB

Bielkegatan 1A

We hereby certify that the Quality System of Ilexis AB for design, production, final inspection and marketing of

Software for orthodontic tracing, cephalometric analysis, and visual diagnostic imaging and treatment planning for both orthodontics and maxillo-facial surgery

medical devices in class IIa has been assessed with respect to the conformity assessment procedure according to Annex II (with the exemption of section 4) of Council Directive 93/42/EEC on Medical Devices, as latest amended by Council Directive 2007/47/EC is implemented in Swedish Law by the national regulation LVFS 2003:11, and found to comply with the requirements

This certificate applies to activities performed at

Bielkegatan 1A, SE-582 21 Linköping Sweden

Originally issued	2013-01-17
Decision date	2020-01-29
Expiry date	2023-01-17

Issued by Notified body 0402

Helén Dahl

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Ackred. no 1002
Certification of Management Systems
ISO/IEC 17021-1

Conditions

Validity

The certificate will remain valid until the expiry date, and allows the holder to use RISE notified body identification number 0402 in conjunction with the CE-mark, on products covered by this certificate, provided that the conditions stated below are fulfilled:

- that surveillance audits are performed, with approved result;
- that the company notifies RISE on all modifications on the products, and that the company does not apply the CE-mark to any new or modified products without confirmation from RISE;
- that the company notifies RISE on all significant changes in the quality system, in its activities and/or organization
- that the certificate is not used in a misleading manner, e.g. in marketing activities.
- that the company notifies RISE about vigilance actions, if any.

Basis for certificate

- The documentation presented has been examined and assessed by RISE in accordance with LVFS 2003:11, Annex II.
- A review according to transfer of Notified Body has been performed by RISE.
- RISE file 86469

Surveillance

RISE will perform surveillance inspections to ensure that the company maintains and applies the quality system that is subject of the certificate.

In accordance with the EU Commission recommendations of 2013-09-24, there will also be unannounced audits once per every three years. These audits can be performed at the manufacturers as well as at selected crucial supplier's premises.

Miscellaneous

Additional conditions appear "RISE General Terms – Assignment" and "Rules and process assessment of medical devices as notified body LVFS 2003:11".

Certificate history

Issue	Date	Activity
	17 January 2013	Initial certificate issued by another notified body
1	21 December 2019	Certificate issued
2	29 January 2020	The scope of certification on the Swedish certificate is adjusted with a new translation from English.

Register of products covered by the certificate

Produkt	Typ/ Modell	Artikelnummer	Klass
FACAD	Facad	P_FACD	IIa
FACAD	CLINIVIEW OrthoTrace, single-user, floating	P-FACD-OTS	IIa
FACAD	CLINIVIEW OrthoTrace, multi-user, floating	P-FACD-OTM	IIa

Note: New products in **bold**