Document information					
ID	P-FACD-1.15	Rev date	2023-10-17	Author	Bengt Schmeling
Product code	P-FACD	Product	Facad		
Title	EU Declaration of conformity / English				
Reviewed by	Anders Blom	Date	2023-10-24	Sign	Anders Blom
Approved by	Bengt Schmeling	Date	2023-10-26	Sign	Bengt Schmeling

EU Declaration of conformity

1. Identification of the device

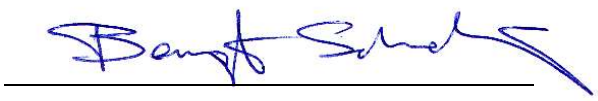
Device name:	FACAD
	Software for orthodontic tracing and cephalometric analysis
Variants:	"Facad Full version", "Facad Tracing Only version"
Device version:	3.14

2. EU Declaration of conformity

Name of the manufacturer:	Ilexis AB
SRN:	SE-MF-000028527
Address of registered place of business:	Bielkegatan 1A, SE 582 21 Linköping, Sweden
Basic UDI-DI:	730000908144FACADAC
Intended purpose:	The product Facad is a software program used for orthodontic tracing, cephalometric analysis, and visual imaging, as well as for treatment planning with soft tissue profile prediction for both orthodontics and maxillo-facial surgery.
Risk class:	MDR class I
Reference to any CS used and in relation to which conformity is declared:	-
Name and identification number of the notified body:	-
Conformity assessment procedure performed:	MDR annex I, II
Identification of the certificate or certificates issued:	-
Additional information:	-

This declaration of conformity is issued under the sole responsibility of the manufacturer.
The device that is covered by the present declaration is in conformity with Regulation (EU) 2017/745.

Linköping 2023-10-17



Bengt Schmeling, CEO