

Declaration of Conformity

Manufacturer	DIRECTA AB P.O. Box 723 SE-194 27 Upplands Väsby, Sweden Street address: Finvids väg 8, Upplands Väsby
Product name(s)	ANA Etching Gel
REF	1510400
Intended Use	Dental gel etchant. Phosphoric acid. To be used by dentists.
Classification	Class IIa (rule 6)
Conformity Assessment	Annex II of MDD 93/42/EEC
Product standards applied	N/A
Notified body	Intertek Semko (0413)
Valid until	2024-05-25

We declare that the medical device mentioned above meets the applicable requirements of the Swedish law 1993:584 concerning medical devices and of the relating regulations set out in LVFS 2003:11 established by the Swedish Medical Products Agency. Thereby, this device is found to be in conformity with the essential requirements and to meet the provisions of Council Directive 93/42/EEC for medical devices.

Upplands Väsby, 2020-03-01



Henric Karsk
Managing Director

*First version of Declaration of Conformity issued year 2016.
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