

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)	CALASEPT® CALASEPT® Plus
REF	1230100, 1230200, 1240100
Intended Use	Endodontic dressing material. Calcium hydroxide. To be used by dentists.
Classification	Class IIa (rule 8)
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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