DIRECTA
directadental.com

Declaration of Conformity

Manufacturer	**DIRECTA AB** Box 723 194 27 Upplands Väsby, Sweden Street address: Finvids väg 8, Upplands Väsby
Product name(s)	**Luxator® Periotome** 1) **Luxator® Short Periotome** 2) **Luxator® Dual Edge Periotome** 3) **Luxator® Periotome Titanium** 4) **Luxator® Dual Edge Periotome Titanium** 5) **Luxator® Forte Elevator** 6) **Luxator® P-series** 7)
Intended use and users	Instrument for manual tooth and root extraction. Used by dentist.
REF	1) 506340, 506341, 506342, 506343, 506352, 506353, 506354, 506355, 506330, 506331, 506332 2) 506358, 506359, 506360, 506361, 506362, 506333 3) 506356, 506357 4) 506433, 506434, 506436 5) 506435 6) 506370, 506371, 506372, 506373 7) 506631, 506632, 506633, 506634, 506635
Classification	Class I, rule 6
Conformity assessment	Annex VII of MDD 93/42/EEC
Registration information	These medical devices are registered with the Swedish Medical Products Agency.

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, 2020-05-14

Henric Karsk
Managing Director

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