



DECLARATION OF CONFORMITY

Revised: 2019-11-20

Distributor

***NORDISKA DENTAL AB
Box 1082
S-262 21 ÄNGELHOLM
SWEDEN***

and manufacturer

**Wykle Research
2222 E. College Parkway
Carson City, NV 89706
USA**

declare according to MDD 93/42/EEC Annex V that our product(s)

Modell: ***ANA 2000 High Copper Admix Alloy:
-Powder
-Capsules
-Duett***

Type of material: ***Dental Alloy filling material***

Class of material: ***II:a***

Notify Body: ***Dekra Certification B.V. (NB0344)***

to which this declaration relates is in conformity with the following standard(s)
or other normative documents

***ISO 24234:2015 Mercury and alloys for dental amalgam
ISO 14971:2012 Medical Devices – application of risk management to
medical devices***

following a quality system based on and in conformance with:

***ISO 13485:2016
Council Directive 93/42/EEC Annex V***

Certificate No. 88253CE01 valid until September 30, 2022

Ängelholm 2019-11-20
NORDISKA DENTAL AB

Mattias Falkheimer
Managing Director