NORDIN®
SWISS DENTAL PRODUCTS
OF DISTINCTION

EC Declaration of conformity

Name and address of the Manufacturer: ***Harald Nordin SA***
ZI La Foge
CH-1816 Chailly / Montreux
SWITZERLAND

By the present document, Harald Nordin SA declares under its sole responsibility that medical devices described in the Reference List (cf. Annex) have been classified as **Class IIa** medical devices:

- Annex IX Rule 5 for Endodontic Reamers and Dentine Pins Drills

and are in conformity with the essential requirements and provisions of **Council Directive 93/42/EEC as amended by Directive 2007/47/EC.**

Related GMDN code for Dental reamers:	31876 – Enlarger, endodontic
Related GMDN code for Dentine pins drills:	36435 – Drill, dental
Basic UDI-DI:	764034297REAMERSQN

The devices are subject to the procedure set out in Annex II (excluding section 4) of Directive 93/42/EEC as amended by Directive 2007/47/EC under the supervision of Notified Body Number 1639.

Notified body

SGS Belgium NV
SGS House
Noorderlaan 87,
BE-2030 Antwerp
Belgium
Certificate n°CH19/0996
Valid until: 24.05.2024

European Authorized Representative (E.A.R.)

WMDE B.V.
Bergerweg 18
6085 AT Horn
The Netherlands
SRN N°: NL-AR-000002062

Chief Executive Officer
Chailly/Montreux, 24th June 2021

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Art.-N°	Product	Quantity	UDI-DI
Peeso Reamers			
02-500	Peeso Reamer RA 28mm Assortment No 1-6	6 Reamers	07640342970499
02-501	Peeso Reamer RA 28mm Refill No 1	6 Reamers Ø0.70	07640342970505
02-502	Peeso Reamer RA 28mm Refill No 2	6 Reamers Ø0.90	07640342970512
02-503	Peeso Reamer RA 28mm Refill No 3	6 Reamers Ø1.10	07640342970529
02-504	Peeso Reamer RA 28mm Refill No 4	6 Reamers Ø1.30	07640342970536
02-505	Peeso Reamer RA 28mm Refill No 5	6 Reamers Ø1.50	07640342970543
02-506	Peeso Reamer RA 28mm Refill No 6	6 Reamers Ø1.70	07640342970550
02-510	Peeso Reamer RA 32mm Assortment No 1-6	6 Reamers	07640342970567
02-511	Peeso Reamer RA 32mm Refill No 1	6 Reamers Ø0.70	07640342970574
02-512	Peeso Reamer RA 32mm Refill No 2	6 Reamers Ø0.90	07640342970581
02-513	Peeso Reamer RA 32mm Refill No 3	6 Reamers Ø1.10	07640342970598
02-514	Peeso Reamer RA 32mm Refill No 4	6 Reamers Ø1.30	07640342970604
02-515	Peeso Reamer RA 32mm Refill No 5	6 Reamers Ø1.50	07640342970611
02-516	Peeso Reamer RA 32mm Refill No 6	6 Reamers Ø1.70	07640342970628
Gates Reamers			
02-600	Gates Reamer RA 28mm Assortment No 1-6	6 Reamers	07640342970635
02-601	Gates Reamer RA 28mm Refill No 1	6 Reamers Ø0.50	07640342970642
02-602	Gates Reamer RA 28mm Refill No 2	6 Reamers Ø0.70	07640342970659
02-603	Gates Reamer RA 28mm Refill No 3	6 Reamers Ø0.90	07640342970666
02-604	Gates Reamer RA 28mm Refill No 4	6 Reamers Ø1.10	07640342970673
02-605	Gates Reamer RA 28mm Refill No 5	6 Reamers Ø1.30	07640342970680
02-606	Gates Reamer RA 28mm Refill No 6	6 Reamers Ø1.50	07640342970697
02-610	Gates Reamer RA 32mm Assortment No 1-6	6 Reamers	07640342970703
02-611	Gates Reamer RA 32mm Refill No 1	6 Reamers Ø0.50	07640342970710
02-612	Gates Reamer RA 32mm Refill No 2	6 Reamers Ø0.70	07640342970727
02-613	Gates Reamer RA 32mm Refill No 3	6 Reamers Ø0.90	07640342970734
02-614	Gates Reamer RA 32mm Refill No 4	6 Reamers Ø1.10	07640342970741
02-615	Gates Reamer RA 32mm Refill No 5	6 Reamers Ø1.30	07640342970758
02-616	Gates Reamer RA 32mm Refill No 6	6 Reamers Ø1.50	07640342970765
Reamers for fibre posts (Glassix and Carbonite)			
02-200	Reamers for Fibre Post Refill L1	3 Reamers Ø1.00	07640342970222
02-201	Reamers for Fibre Post Refill L2	3 Reamers Ø1.20	07640342970239
02-202	Reamers for Fibre Post Refill L3	3 Reamers Ø1.35	07640342970246
02-203	Reamers for Fibre Post Refill L4	3 Reamers Ø1.50	07640342970253
Glassix+ Plus Reamers			
02-310	Glassix +Plus Reamers Refill No 1	3 Reamers	07640342970314
02-311	Glassix +Plus Reamers Refill No 2	3 Reamers	07640342970321
02-312	Glassix +Plus Reamers Refill No 3	3 Reamers	07640342970338
02-313	Glassix +Plus Reamers Refill No 4	3 Reamers	07640342970345
02-320	Glassix +Plus Pilot Reamers Refill	3 Reamers	07640342970352
Nordin Reamers for screw posts			
03-300	Nordin Reamers Assortment S 1-6	6 Reamers 28mm	07640342971465
03-301	Nordin Reamers Assortment L 1-6	6 Reamers 34mm	07640342971472

03-302	Nordin Reamers Refill S1	3 Reamers 28mm Ø1.05	07640342971489
03-303	Nordin Reamers Refill S2	3 Reamers 28mm Ø1.20	07640342971496
03-304	Nordin Reamers Refill S3	3 Reamers 28mm Ø1.35	07640342971502
03-305	Nordin Reamers Refill S4	3 Reamers 28mm Ø1.50	07640342971519
03-306	Nordin Reamers Refill S5	3 Reamers 28mm Ø1.65	07640342971526
03-307	Nordin Reamers Refill S6	3 Reamers 28mm Ø1.80	07640342971533
03-308	Nordin Reamers Refill L1	3 Reamers 34mm Ø1.05	07640342971540
03-309	Nordin Reamers Refill L2	3 Reamers 34mm Ø1.20	07640342971557
03-310	Nordin Reamers Refill L3	3 Reamers 34mm Ø1.35	07640342971564
03-311	Nordin Reamers Refill L4	3 Reamers 34mm Ø1.50	07640342971571
03-312	Nordin Reamers Refill L5	3 Reamers 34mm Ø1.65	07640342971588
03-313	Nordin Reamers Refill L6	3 Reamers 34mm Ø1.80	07640342971595
Dental Reamers for screw posts			
04-400	Dental Reamers Assortment S 1-6	6 Reamers 28mm	07640342972547
04-401	Dental Reamers Assortment L 1-6	6 Reamers 34mm	07640342972554
04-402	Dental Reamers Refill S1	3 Reamers 28mm Ø1.05	07640342972561
04-403	Dental Reamers Refill S2	3 Reamers 28mm Ø1.20	07640342972578
04-404	Dental Reamers Refill S3	3 Reamers 28mm Ø1.35	07640342972585
04-405	Dental Reamers Refill S4	3 Reamers 28mm Ø1.50	07640342972592
04-406	Dental Reamers Refill S5	3 Reamers 28mm Ø1.65	07640342972608
04-407	Dental Reamers Refill S6	3 Reamers 28mm Ø1.80	07640342972615
04-408	Dental Reamers Refill L1	3 Reamers 34mm Ø1.05	07640342972622
04-409	Dental Reamers Refill L2	3 Reamers 34mm Ø1.20	07640342972639
04-410	Dental Reamers Refill L3	3 Reamers 34mm Ø1.35	07640342972646
04-411	Dental Reamers Refill L4	3 Reamers 34mm Ø1.50	07640342972653
04-412	Dental Reamers Refill L5	3 Reamers 34mm Ø1.65	07640342972660
04-413	Dental Reamers Refill L6	3 Reamers 34mm Ø1.80	07640342972677
Ancorex Reamers for screw posts			
05-100	Ancorex Reamers Assortment S 1-7	7 Reamers 28mm	07640342972929
05-101	Ancorex Reamers Assortment L 1-7	7 Reamers 34mm	07640342972936
05-102	Ancorex Reamers Refill S1	3 Reamers 28mm	07640342972943
05-103	Ancorex Reamers Refill S2	3 Reamers 28mm	07640342972950
05-104	Ancorex Reamers Refill S3	3 Reamers 28mm	07640342972967
05-105	Ancorex Reamers Refill S4	3 Reamers 28mm	07640342972974
05-106	Ancorex Reamers Refill S5	3 Reamers 28mm	07640342972981
05-107	Ancorex Reamers Refill S6	3 Reamers 28mm	07640342972998
05-108	Ancorex Reamers Refill S7	3 Reamers 28mm	07640342973001
05-109	Ancorex Reamers Refill L1	3 Reamers 34mm	07640342973018
05-110	Ancorex Reamers Refill L2	3 Reamers 34mm	07640342973025
05-111	Ancorex Reamers Refill L3	3 Reamers 34mm	07640342973032
05-112	Ancorex Reamers Refill L4	3 Reamers 34mm	07640342973049
05-113	Ancorex Reamers Refill L5	3 Reamers 34mm	07640342973056

05-114	Ancorex Reamers Refill L6	3 Reamers 34mm	07640342973063
05-115	Ancorex Reamers Refill L7	3 Reamers 34mm	07640342973070
Nordin Drills for titanium dentine pins			
06-005	Nordin Titanium Dentine Retention Pins Drill, 0.60mm	1 Drill	07640342973148
06-006	Nordin Titanium Dentine Retention Pins Drill, 0.75mm	1 Drill	07640342973155
Dental Drills for titanium dentine pins			
06-104	Dental Titanium Dentine Retention Pins Drill, 0.60mm	1 Drill	07640342973209
06-105	Dental Titanium Dentine Retention Pins Drill, 0.75mm	1 Drill	07640342973216