

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 8 for Fiber Posts

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: 38609 – Root canal post, prefabricated

Basic UDI-DI: 764034297GLASSFIBERCP

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.
Bergeweg 18
6085 AT Horn
The Netherlands
SRN N°: NL-AR-000002062*

*Chief Executive Officer
Chailly/Montreux, 24th June 2021*

Art.-N°	Product	Quantity	UDI-DI
02-001	Glassix Kit	3x6 Glassix + 3 Reamers	07640342970123
02-002	Glassix Refill No 1	6 Glassix	07640342970130
02-003	Glassix Refill No 2	6 Glassix	07640342970147
02-004	Glassix Refill No 3	6 Glassix	07640342970154
02-005	Glassix Refill No 4	6 Glassix	07640342970161
02-300	Glassix +Plus Kit	4x5 Glassix +plus + 4x1 Reamer + 1 Pilot Reamer	07640342970260
02-301	Glassix +Plus Refill No 1	10 Glassix +plus	07640342970277
02-302	Glassix +Plus Refill No 2	10 Glassix +plus	07640342970284
02-303	Glassix +Plus Refill No 3	10 Glassix +plus	07640342970291
02-304	Glassix +Plus Refill No 4	10 Glassix +plus	07640342970307