

DECLARATION OF CONFORMITY

Regarding Medical Device Directive(93/42/EEC)
including Directive 2007/47/EC

Manufacturer CHENGDU SANI MEDICAL EQUIPMENT CO.,LTD.
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EC Representative SUNGO Europe B.V.
Address Olympisch Stadion 24, 1076DE Amsterdam,Netherlands
UMDNS Code 16662
Product Name Root Canal File
Model See Annex
Classification Class I (MDD, Annex IX,Rule 6)
Conformity Assessment Annex V of Medical Device Directive(93/42/EEC)
Procedure

We herewith declare that the above-mentioned products meet the requirements of Medical Device Directive (93/42/EEC) and the following harmonized standards.

EN ISO 3630-1:2019

EN ISO 3630-5:2020

EN ISO 14971:2019

EN ISO 15223-1:2016

EN ISO 10993-1:2020

EN ISO 10993-5:2009

EN ISO 10993-10:2013

Signature: 

Name/ Position: Chunxia HE/ GM

Date: 2022-05-05

Place: China/ Chengdu



Annex

Root Canal File Model

Model	Specification	
	operative part length	Nominal specification code
K Files、 H Files、 Reamers	21mm、25mm、28mm、 31mm	06、08、10、12、15、17、20、22、25、27、 30、32、35、37、40、45、50、55、60、70、 80、90、100、110、120、130、140
U Files	32mm、35mm	15、20、25、30、35、40
Super C	19mm、21mm、25mm、 28mm、31mm	06、08、10、12、15、17、20