EC Declaration of Conformity

This declaration of conformity is issued under the sole responsibility of
ENRAF-NONIUS B.V., Vareseweg 127, 3047 AT Rotterdam, The Netherlands

Quality Management System according to ISO 13485:2016, EN ISO 13485:2016 and
Annex II (excl. section 4) of European Medical Devices Directive 93/42/EEC.
Approval No. HD 60108762 001
Notified body: TÜV Rheinland LGA Products GmbH (0197), Tillystraße 2, 90431 Nürnberg, Germany

Device name:	Sonopuls 190
Description:	Ultrasound Therapy Equipment
Article number(s):	1631.901/902/903/904
Classification:	IIa (according to rule 9, Annex IX of MDD 93/42/EEC)
Record of conformity:	026-400-290-44 ER
Device marking:	CE0197

We hereby declare that the above-mentioned device
complies with the European Medical Devices Directive 93/42/EEC.

This declaration of conformity is valid in combination with the test certificate of the device.
Any modifications to the product not authorized by Enraf-Nonius will invalidate this declaration.

Rotterdam, 26 May 2020

Signature:

Th.L. Boodkorte
Director

A. van Maurik
QA Manager