



## 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 of European Medical Devices Directive 93/42/EEC.

Approval No. HD 60108762 001

Notified body: TÜV Rheinland LGA Products GmbH (0197)

Device name:	Occiflex
Description:	Treatment couch
Article number(s):	1660901
Classification:	Ila (according to rule 9, Annex IX of MDD 93/42/EEC)
Record of conformity:	026-400-249-4 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 authorised by Enraf-Nonius will invalidate this declaration.

Rotterdam, date: 02 September 2019

Signature:

  
A. van Maunck  
QA-manager