

Declaration of Conformity

for the product

Tensio Wrist – PN 13828

We, Société Terraillon S.A.S., 1 rue Ernest Gouin, 78290 Croissy sur Seine, France, declare under our sole responsibility that product indicated above is compliant with essential requirements of health, safety and performances. This product complies with requirements of the **Directive 93/42/EEC concerning medical devices** and complies with the standards listed below:

Rapport GZME150400026101	EN 60601-1-2 : 2014
Rapport RZ12090024	IEC 60601-1-11 : 2011
Rapport 64.66T.12.085.02	EN 1060-3
Rapport 64.66T.12.083.01	EN 1060-1

Notified Body :

TÜV SUD Product Service GmbH
Ridlerstrasse 65 – 80339, Munchen, Germany

This product carries the CE 0123 which was first affixed in 2019

Croissy sur Seine, 18th November 2020

Quality Manager
Frederic DAGGAG