EC Declaration of Conformity

Manufacturer:

Artron Laboratories Inc.
3938 North Fraser Way, Burnaby, BC, V5J 5H6, Canada

whose single Authorized Representative:

MedNet EC-REP GmbH
Borkstrasse 10 · 48163 Muenster · Germany

We, the manufacturer, herewith declare that the products

Male Fertility Sperm Test (Sperm OK) for self-testing
Cat No.: A01-06-422 (Cassette)
Analyte of the Test: Male Fertility Sperm
UMDNS-Code: 17-418; EDMA Code 12.70.05.90

meet the provisions of Directive 98/79/EC which apply to them.

The medical device has been assigned to devices for self-testing according to the Directive 98/79/EC. It bears the mark

CE 0197

The product concerned has been designed and manufactured under a quality management system according to Annex IV of Directive 98/79/EC.

Compliance of the designated product with the Directive 98/79/EC has been assessed and certified by the Notified Body

TÜV Rheinland LGA Products GmbH
Tillystraße 2, 90431, Nürnberg, Germany
Certificate No.: HL 1272611-1
Effective date: 2022-05-12
Issue date: 2022-05-12
Expiry date: 2029-12-31

following the procedure relating to the EC Declaration of Conformity set out in Annex IV of Directive 98/79/EC.
This Declaration of Conformity covers all medical devices as specified in the product list belonging to this declaration and is only valid in connection with a batch specific Certificate of Compliance for all products concerned bearing the CE mark.

The above-mentioned declaration of conformity is exclusively under the responsibility of

Artron Laboratories Inc.
3938 North Fraser Way, Burnaby, BC, V5J 5H6, Canada

Burnaby, May 20, 2022
Place, date

RA Manager
Legally binding signature, Function