

DECLARATION OF CONFORMITY

TROGE MEDICAL GMBH

We.....

Name of the Manufacturer

Milchstrasse 19, 20148 Hamburg, Germany

.....
Address of the Manufacturer

hereby declare under our sole responsibility that the product

Designation: *TRO-DONEX-1 / TRO-DONEX-2, TRO-DONEX-3, TRO-DONEX-4, Blood Bags, single, double, triple, quadruple in different sizes with CPDA-1 solution or CPD solution optionally with transfer bags, or combination in different sizes with CPD solution and SAGM solution in two separated bags (CPD solution in blood collection bag, SAGM solution in one transfer bag) and optionally with additional transfer bags TRO-DONEX-4, Blood Bags quadruple optional with top and bottom position of the tubes (2 on top, 2 on bottom of a bag) TRO-DONEX-1 safety / TRO-DONEX-2 safety / TRO-DONEX-3 safety / TRO-DONEX-4 safety, Safety Blood Bags, single, double, triple, quadruple with transfer bags and in different sizes with CPDA-1 solution or CPDA-1 solution in blood collecting bag and SAGM solution in one transfer bag*

Type: *Plastic Collapsible Blood Bags*

Medical Device Class: *II b, rule 18*

complies with applicable product standards and furthermore meets the essential requirements stipulated in ANNEX I of the Medical Devices Directive 93/42/EEC of 14th June 1993 as amended by 2007/47/EC.

Conformity Assessment Procedure was carried out according Annex II respectively V of MDD 93/42/EEC as amended by 2007/47/EC and is certified by the following Notified Body:

Name, Address and ID No.:

*TÜV NORD CERT GMBH, ID No. 0044
Langemarkstrasse 20, 45141 Essen, Germany*

under CE Certificate No.: 44 232 034387

This declaration of conformity is valid until 24.11.2023.

Hamburg, 05.09.2019

Place and Date

TROGE MEDICAL GMBH
Milchstr. 19 D-20148-Hamburg Tel. 44 18 44-0

.....
Signature of the responsible person
Thomas Tilgner
(Managing Director)