



EC-Declaration of Conformity for CE-Marking

According to Council Directive 93/42/CE modified by the council directive 2007/47/EEC.

Déclaration de Conformité pour marquage CE

Conformément à la directive 93/42/CE modifiée par la directive 2007/47/CE.

EG-verklaring voor de CE-markering

Volgens de richtlijnen 93/42/CE, gewijzigd door Council Directive 2007/47/EEC.

EG-Konformitätserklärung für CE-Kennzeichnung

Gemäß der Council Richtlinie 93/42/CE modifiziert über die Council Richtlinie 2007/47/EEC.

Manufacturer/Fabricant/Fabrikant/Produzent

ONTEX BV, Genthof 5, 9255 Buggenhout, Belgium

Registration number/ N° d'enregistrement/Registratienummer/ Registrierungsnummer

BE/CA01/1-00316

Product/Produit/Produkt/Produkte

Medical Masks Type IIR

Product category/ Catégorie de produit/ productcategorie/ Produktkategorie

Medical Masks

Risk classification/ Classification du risque/Risico classificatie/ Risikoklassifizierung

Class I products non-sterile

Conformity assessment route/ Parcours d'évaluation de la conformité/ Conformiteitsbeoordeling/

Konformitätsbewertung.

Annex VII of MDD

We hereby declare that the above-mentioned products are under development and will meet the provisions of the Council Directive 93/42/EEC modified by the directive 2007/47/EEC. All supporting documentation will be retained at the premises of the manufacturer.

Applicable standards/ Standards applicable/ geldende normen/ geltende Normen

ISO 9001:2015

EN 14683:2019

ISO 13485:2016

Notified body/ Organisme tierce partie/ aangemelde instantie / notifierte Stelle

Not applicable/ non applicable/ niet van toepassing/ nicht anwendbar

EC-certificates/ Certificats de conformité/ EG-certificatie/ EG-Zertifikate

Not applicable/ non applicable/ niet van toepassing/ nicht anwendbar

Place/lieu/plaats/Platz

Aalst

Buggenhout

Name/nom/naam/Name

Position/fonction/functie/Posten

K Cardoen

VP Quality

Date/date/datum/Datum

28/09/2020