CERTIFICATE

O+ OPLUS FRANCE ALSACE PROTECTION

This is to certify that the product listed below conforms to the requirements of the

Directives Name MEDICAL DEVICES 93/42/EEC

Certificate no.: FR9261U-2020 **Date of Expiry:** 21 December 2023

Date of Issue: 22 December 2020 **Sur :** 21 December 2021

Manufacturer : **O+PLUS ALSACE PROTECTION FRANCE**

11 ROUTE DE BRUMATH 67800 / HOENHEIM / FRANCE

Description of Products : GLOVE(CLASS 1, NON STERILE)

Equipment Identification : As Shown of Above

Other Certification : ISO 13485:2016, 9K, 14K

Standards Applied : EN ISO 374-1:2016

Report Reference: OPAPF/CE/FR9261U-2020

This Report has been Issued by Certiva Limited according to the provision of the **Medical Device Directive (European Economic council).** This Report is issued following the assessment of the documentation and implementation of the Quality System in accordance with the provisions of the quoted Conformity Assessment Module of the above directives. The CE Mark may be affixed to the press **Medical Device Directive** the Scope of approvals as described above once the 'EU declaration of conformity' has been signed by the responsible person.

CE

Director

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