



EU DECLARATION OF CONFORMITY

1. PPE: **POWDER FREE NITRILE GLOVE, NON-STERILE, "OMEGA LINE CHEMO B"**
2. Manufacturer's name and address:
CELULOSAS VASCAS, S. L.
Parque Empresarial Boroa, parcela 2A-1B, 48340, Amorebieta (Bizkaia)
3. Current declaration of conformity is issued under the responsibility of the manufacturer: **CELULOSAS VASCAS, S.L.**
4. Declaration purpose: **POWDER FREE NITRILE GLOVE, NON-STERILE, "OMEGA LINE CHEMO B"**



5. The purpose of the declaration described in point 4 above is in accordance with the applicable Union harmonization legislation **425/2016 EU Regulation, for Personal Protective Equipment and 93/42 European Directive 93/42 for Medical Devices (Class I)**.
6. References to the applicable harmonized standards used, including their dates, or references to the other technical specifications, including their dates, for which conformity is declared: **EN 420:2003+A1:2009, EN ISO 374-1:2016/A1:2018 and EN ISO 374-5:2016 that are applicable, as PPE against high risks (CAT III)**
7. Notified Body **SATRA (N° 2777)** has carried out EU Type Examination (module B) and has issued EU Type Certificate **N° 2777/12470-02/E00-00**.
8. The PPE is subject to the conformity assessment procedure with the type based on internal production control plus supervised control of products at random intervals (module C2), under the supervision of the notified body **SATRA (N° 2777)**
9. Additional information: N/A



Signed by **XABIER PANERA LIÑEIRO** (Charge: Technical Manager)
In name of the company **CELULOSAS VASCAS, S. L.**

AMOREBIETA, 22th OF JANUARY OF 2019