

DECLARATION OF CONFORMITY



The undersigned CALZE GT Srl, based in CASALOLDO (MN), Via W. Tobagi 17/21, declares under its sole responsibility that the medical devices "RELAXSAN UNIMA multipurpose masks" with codes "MASK-01S and KIDS-MASK- 01S "belong to risk class I (non-sterile), in accordance with rule 1 of Annex IX of Directive 93/42 / EEC and subsequent amendments (implemented in Italy with Legislative Decree 24 February 1997, n. 46, and subsequent amendments),

- they comply with the essential requirements and the provisions of Directive 93/42 / EEC and subsequent amendments as per Technical File no. FT 012 GC filed at the Company.
- are manufactured in accordance with the Quality System that meets the requirements set out in Annex VII of Legislative Decree n. 46 of 24/02/97 and subsequent amendments.
- comply with the UNI EN 14683: 2019 - Type I standard.



CALZE G.T. SRL
Via Walter Tobagi, 17/19/21
46040 CASALOLDO (MN)
C.F. 01380780203
P.IVA: IT 01380780203

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The legal representative
Gorgaini Cristiano

CASALOLDO (MN), date 13/03/2021