ERVE SCHUSTER
HYGIENE-EXPERTEN

ERVE Deutschland GmbH · Wankelstraße 22 · 50996 Köln

EU Declaration of Conformity

The manufacturer ERVE Deutschland GmbH declares that the product described hereafter:

ERVE 995 Plus beige

is in conformity with the

1) **Medical Device Regulation (EU) 2017/745,** under Class I Medical Device per set out in Rule 1 and Rule 5 of Annex VIII, complying with the European standards EN 455-1:2000, EN 455-2:2015, EN 455-3:2015, and EN 455-4:2019.

And

2) **Personal Protective Equipment Regulation (EU) 2016/425**, under Category III risk per set out in Annex I, complying with the European standards EN 420:2003+A1:2009, EN ISO 374-1:2016+A1:2018, EN ISO 374-5:2016. It is identical to the PPE which is subject the the EU Type Examination (Module B) under certificate number 2777/11630-01/E10-01 issued by Notified Body:

SATRA Technology Europe Limited (2777)
Bracetown Business Park, Clonee, Dublin 15, D15 YNP, Ireland

and is subject to the annual conformity assessment procedure which is based on internal production control plus supervised product checks at random intervals (Module C2) under surveillance of the Notified Body:

SATRA Technology Europe Limited (2777)
Bracetown Business Park, Clonee, Dublin 15, D15 YNP, Ireland

The above mentioned product demonstrates fulfilment to the essential health and safety requirements set out in Annex II of PPE Regulation (EU) 2016/425.

Signature:

Name: Anna Fast
Position: General Manager
Date: Cologne, 03.03.2020