

Testing and certification of masks.

Ensure safety and trust during the COVID-19 pandemic.


During the COVID-19 pandemic, the demand for protective equipment such as FFP2 masks or medical masks has increased dramatically. Many companies quickly included these articles in their production lines. This has led to poor product quality in the past and caused uncertainty among end users and distributors. TÜV Rheinland will also make its contribution in the pandemic and tries to ensure the quality of the products for buyers, traders and users with product testings and certification. Driven by that idea, TÜV Rheinland expended the service portfolio around the demanded products.

FFP2 MASKS – TESTING AND CERTIFICATION

Manufacturers can have their particle filtering masks, colloquially known as respirators, tested and certified in the laboratories of TÜV Rheinland. For certification the products must comply with the requirements of the relevant Regulation 2016/425 for Personal Protective Equipment. Manufacturers usually achieve this by applying the harmonized standard EN 149:2001+A1:2009. Manufacturers are then allowed to mark the masks with a CE mark and place them on the European market as personal protective equipment. Masks certified by TÜV Rheinland can be recognized by the Notified Body number as listed on the [NANDO](#) page.

FFP2 masks

- ✓ PPE category III



EU requirements

- ✓ DIN EN149:2001+A1:2009
- ✓ CE mark (EU 2016/425)

US requirements

- ✓ CDC NIOSH N 95

FACE SHIELDS – PRODUCT TESTING


TÜV Rheinland offers testing and certification for face shields based on DIN EN 166:2002-04 and Regulation (EU) 2016/425 for PPE products. After successful testing of all criteria, manufacturers receive the EU-type examination certificate and can affix the CE mark on their product.

MEDICAL MASKS – TESTING AND CERTIFICATION.

TÜV Rheinland offers certification with the voluntary test mark „[Tested Medical Device](#)“, which displays the quality of your masks. The prerequisite for this is product testing according to the European standard EN 14683:2019, a review of the technical documentation and a factory inspection. After successful completion, you will receive a certificate and can label your product with the corresponding test mark. We also gladly support you with tests that are relevant to the markets in the USA or China.

Medical masks

- ✓ Medical device, class I



EU requirements

- ✓ CE mark (MDD 93/42/EWG or MDR EU 2017/745)
- ✓ Medical devices class I or Is
- ✓ DIN EN 14683:2019-10
- ✓ Additional: EN ISO 10993-1, EN ISO 11737-1

US requirements

- ✓ ASTM F2100 level 2 or 3
- ✓ ASTM F2101
- ✓ MIL-M.36945C
- ✓ ASTM F4862-07
- ✓ ISO 2859-1 or ANSI/ASQC Z1.4

COMMUNITY MASKS – TESTING AND CERTIFICATION.

For the so-called community masks, TÜV Rheinland offers product testing in accordance with the regulatory requirements. Additionally, we offer a testing based on the criteria catalog of the internal [test specification](#) (2PFG S 0193/04.20). Upon successful completion of the testing, masks can be certified with the TÜV Rheinland test mark 'Schadstoffgeprüft' (Tested for Harmful Substances).

THERE ARE MANY GOOD REASONS.

- Verification of your quality statement by an impartial testing service provider
- Clear guidance and decision-making aid for your customers
- Differentiation from your competitors

SIMPLE. QUICK. EVERY WHERE.

Our international expertise and excellent network have enabled us to attract competent partner laboratories for testing the masks. This allows us to perform fast and flexible testing of masks worldwide.

Any questions?

Learn more about the services we provide – www.tuv.com

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