Medical Masks – Get your Certification.

TÜV Rheinland gives you quick and easy access to the European market.

Medical masks are a more cost-effective alternative to FFP2 masks during the COVID-19 pandemic. They differ from FFP2 masks especially in their intention to protect primary the people around and not the wearer of the mask. They are classified as a Class I or Is non-active medical device and subject to the requirements of the Medical Devices Directive 93/42/EEC or the Medical Devices Regulation (EU) 2017/745. Therefore, they require a CE marking in order to be placed on the European market.
During the COVID-19 pandemic, media reports about faked or substandard medical masks are undermining the confidence of end consumers in the quality of these products. In addition, manufacturer are allowed to affix the CE mark by themselves on their Class I medical devices.

Medical Masks Testing and Certification

CE

Product testing

- EN 14683:2019+AC:2019
- Chemical testing
- Biocompatibility testing according to EN ISO 10993-5 and EN ISO 10993-10
- Results in 30 days
- Verification by an impartial testing service provider

Medical masks

- Non-active medical device class I or Is
- Protection against infectious droplets
- Protects others – offers only partly self-protection

CE mark

- **Mandatory** for the European market access
- Regulatory requirements for CE mark: Medical Device Directive 93/42/EEC and after May 2021, 26 the Medical Device Regulation (EU) 2017/745

VISIBLE QUALITY THANKS TO THE GM MARK

Beyond the testing and issuance of test reports for medical masks, TÜV Rheinland also offers the voluntary certification „Geprüftes Medizinprodukt" (Tested Medical Device). Affixed on your medical mask, this test mark demonstrates the high product quality and is forgery proofed via the associated QR code. Having your products certified by a neutral third party clearly sets you apart from the competition and shows consumers that you are a reputable and reliable medical device provider.

YOUR WAY TO THE GM MARK

Preparing for your GM certification is basically similar to most medical device regulation certification processes and is a good opportunity to carefully review your existing processes, workflows, and production and documentation.

As part of our certification process, our experts subject the technical documentation of your medical device to a thorough review in accordance with the requirements of the Medical Devices Ordinance.

In addition, your medical devices themselves undergo a series of tests. If your products have achieved a positive result, the next step is to plan and carry out an on-site inspection of your manufacturing facility. If this is also successfully completed, you will receive the final result with our official test report and certificate. This allows you

How to obtain GM marking?

to affix the GM mark to your product. The unique identifier stands for a unique seal of quality, for which you will receive a corresponding QR code that can be scanned by customers around the world. In addition, the entry is made in our certificate database Certipedia.

INTERNATIONAL TESTINGS

Beside the certification, we have full capacity to carry out the complete suite of tests for type I, II and IIR medical masks required by EN 14683:2019.
In order to support our customers with market access in the US we are able to test partly to the FDA acknowledged standard ASTM F 2100-2019. In order to support Chinese market access, our laboratory network can also deliver tests according to the Chinese Standard YY0469.

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

FOR MORE INFORMATION, PLEASE CONTACT OUR SALES REPRESENTATIVES:

Nina Marx
Tel. +49 221 806-2984
nina.marx@de.tuv.com

Christian Schacherl
Tel. +49 221 806-1408
christian.schacherl@de.tuv.com

TÜV Rheinland LGA Products GmbH
Tillystraße 2
90431 Nuremberg, Germany
Tel. +49 911 655-5225
Fax +49 911 655-5226
service@de.tuv.com

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Precisely Right.