msg advisors

CE MARKING GUIDELINES

YOUR CONSULTING PARTNER FOR THE HEALTHCARE INDUSTRY

msg advisors helps with your conversion to or commencement of the production of non-sterile / sterile surgical masks for medical professionals

With recommendation (EU) 2020/403, the European Commission has temporarily relaxed the strict rules governing the domestic market in order to help manage the current demand for protective equipment during the Corona pandemic. Consequently, they will allow non-sterile surgical respirators that do not have the CE mark to be delivered to medical professionals. In addition, a last minute decision was also made to extend the transition period for switching from the "old" EU 93/42/EWG guideline to the new EU 2017/745 ordinance. Both the guideline and the ordinance serve to regulate the introduction of medical devices to the market and both require a CE marking before goods can move freely.

Manufacturers are allowed to independently affix the CE mark if they can ensure the systematic satisfaction of the fundamental safety and performance requirements. The requirements themselves can be found in Annex I of the guideline or ordinance. A considerably higher number of requirements must be met for a CE marking and unlimited access to the domestic market.

Avoid incalculable costs

This raises an important question for all companies involved: what happens to the investment / new production when the EU Commission puts the strict rules back into place? At that point, the necessary EU conformity assessment procedure can quickly prove to be a difficult hurdle.

To avoid this hurdle, companies should take a long-term view and act accordingly, even as they follow the Commission's simplified procedure. Uncertainty or ill-considered actions can quickly lead to incalculable costs.

After all, it is fairly safe to assume that the demand for protective equipment will last for quite a while and that non-medical professionals will also declare a need for it! Yet, a CE marking will be necessary for longer-term activity on the market.

To help companies turn this long term prospect into a reality when converting to or commencing production, msg advisors has developed the following consulting program.

Your contact partners:

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Surgical mask production: let msg advisors help you secure long-term prospects

"Simplified" procedure as per recommendation (EU) 2020/43

Administrative aspects and notification obligations

Limiting liability risks:
- Found separate / new company
- Sign commercial liability insurance policy*
- Agreements / contracts with suppliers

Notification obligations as per the Medical Devices Act:
Create a DIMDI (German Institute for Medical Documentation and Information) account

** MDR requirements effective 05/25/2021*

DIN EN 14683:2019 certification

Clear definitions and certifications:
- Material procurement and goods receipt
- Production processes
- Inspections

Presentation of well-controlled production to ensure standard requirements are met at all times

How we can help

msg can help you
- Meet notification obligations
- Prepare a pragmatic risk management system as the basis for decisions
- Vendor management

msg can help you establish efficient and suitable
- Procurement processes and specifications
- Production specifications and certificates
- Interim or final inspections, as well as inspection protocols

For proof of quality at any time

TEMPORARY Delivery only of NON-STERILE products WITHOUT a CE mark to medical professionals

Our offer for your future: The EU internal market with CE

Long-term satisfaction of legal requirements

Transfer to Directive 93/42/EWG

Clear definitions and certifications:
- Satisfaction of basic requirements
- Corrective/preventative measures
- Process validation

EU conformity assessment procedure as per Directive 93/42/EWG Annex VII for non-sterile / Annex V for STERILE surgical masks

Transfer to Regulation (EU) 2017/745

Clear definitions and certifications:
- Basic safety / performance requirements
- Quality management as per Art. 10 of the MDR
- Agreements / contracts with suppliers

EU conformity assessment procedure as per Regulation 2017/745/EWG for non-sterile / or STERILE surgical masks

msg can help create a certifiable quality management system for
- Creating / maintaining technical documentation
- Complain management / market observations as per §29 of the Medical Devices Act
- Interim staffing of a safety officer for medical devices as per §30 of the Medical Devices Act:

msg's help with and certification preparation for
- Interim staffing of responsible person as per Art. 15 of the MDR
- Risk management file as per DIN EN ISO 14971
- Technical documentation as per Annex II & III

Surgical masks without a CE marking can no longer be delivered!
CE marking required for general delivery in the EU internal market

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