

## Checklist for Masks for the German Federal Ministry for Health

Manufacturer / Supplier: .....

Order/Contract ID: .....

Location of examination: .....

Date and time of examination: .....

Name of examiner: .....

**All Check items should be fulfilled.**

	Aspect	Test item	Goal	Fulfilled ?
	Documents, Certificates	Certificates according to standards: <ul style="list-style-type: none"> <li>• DIN EN 14683:2019-6</li> <li>• DIN EN 149:2001-10</li> <li>• United States NIOSH-42CFR84</li> <li>• KN95 (China GB2626-2006)</li> <li>• P2 (Australia/New Zealand AS/NZS 1716:2012)</li> <li>• Korea 1st class (Korea KMOEL - 2017-64)</li> <li>• DS (Japan JMHLW-Notification 214, 2018)</li> </ul>	At least one of the mentioned certificates is reliably documented.  If other standards than the mentioned ones are documented, their applicability may be checked by BfArM: please send Scans/photos of the documents/certificates to BfArM ( <a href="mailto:9@bfarm.de">9@bfarm.de</a> and <a href="mailto:92@bfarm.de">92@bfarm.de</a> ) and BfArM will check them as quickly as possible.	

	Labelling	<p>The packages are labelled in:</p> <ul style="list-style-type: none"> <li>• English</li> <li>• German</li> </ul>	<p>Packages are readably labelled in one of the mentioned languages and the content of label and description is adequate.</p> <p>Also exceptionally acceptable if labelled in Chinese only.</p>	
	Packages (individual as well as overall)	Status of the packages	<p>The packages are</p> <ul style="list-style-type: none"> <li>• dry</li> <li>• undamaged</li> <li>• clean</li> </ul>	
	Completeness	Number of masks in packages	The number of individual masks in small packages as well as of small packages in whole packages (bind) is as specified.	
	Design and color	Design and color of masks	<p>The design and color of the masks is according to positive samples of verified quality (if available, see sample pictures below).</p> <p>The masks are regularly folded or shaped (see sample pictures below).</p> <p>The fixation of elastic or non-elastic bands is stable. Please check by manual tearing several times.</p> <p>The fixation piece for the nose (for surgical masks) is easily bendable several times and reliably keeps its shape after bending.</p>	

	FFP 2 / FFP 3 / Medical Masks	Design	<p>If the masks are surgical masks they should look similar to the respective pictures below (with closed or open head/ear straps, elastic or non-elastic)</p> <p>If the masks are personal protection masks (FFP 2 or FFP 3) they should look similar to the respective pictures below and may or may not have an exhale valve.</p>	
	Haptics	Haptics of the mask	The haptic feeling of the masks is according to positive samples of verified quality (if available).	
	Shape and wearing	Shape and wearing test of the mask.	<p>The shape and fit of the masks is according to positive samples of verified quality (if available).</p> <p>The mask fits well and tight on the face (FFP2/3 masks should be in complete contact with the skin, medical masks should cover nose and mouth as well as cheeks) even when moving the head rigidly.</p> <p>The fit stays constantly good even during at least five iterations of wearing and removing the mask.</p>	
	Smell	Smell of the mask	The smell of the masks is according to positive samples of verified quality (if available).	

			<p>No strange or disgusting smells are identified.</p> <p>No mould smell is identified.</p>	
	Content / Material	<p>Destructive testing (please cut at least five sample masks from different packages with a scissor and inspect the inside):</p> <ul style="list-style-type: none"> <li>• Number and material of layers</li> <li>• Haptic and optical inspection of the filter material and the upper and lower layer</li> </ul>	<p>A filter fleece with control of the layers and complete filling of the fleece pocket with filter fleece is identifiable.</p> <p>There is at least one filter fleeces layer identifiable.</p> <p>There are no sharp edges visible at the fleece.</p>	

Date and Signature of examiner: .....

Examples of look /design of medical/surgical masks:



Examples of look /design of masks of self-protective equipment (FFP 2 / FFP 3) with or without exhale valve:

