

# amoena

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28.06.2022

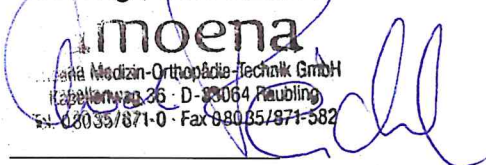
## Producer statement

### IFU for Breast Care Apparel

According to the Medical Device Coordination Group (MDCG), instructions for use are not required for class 1 medical devices as long as the safe use of the devices is guaranteed. (Source: <https://www.johner-institut.de/blog/regulatory-affairs/medizinprodukte-der-klasse-1/#:~:text=conclusion>)

As our bras (NOS, OTS and Cura Support Comfort) and swimwear are class 1 medical devices and are safe to use, an instructions for use is not included in the packaging.

Raubling , 28.06.2022

  
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