

TEKNISK BULLETIN

INFORMATION FRÅN VADEXIT

2012-08-24

Nr 50

Virkon, Perasafe och CE-märkning

Många frågar sig varför Perasafe är CE-märkt, men inte Virkon och vi har därför bett DuPont om ett klagörende.

There is an ISO guidance document that clarified the situation and it categorically states that the CE mark can only be applied when the label only claims Medical Device usage.

If there were to be dual claims on a product label, then the CE mark needs to be removed and the product regulated within the bounds of the BPD (Biocidal Products Directive). This is due to the wording of the Medical Devices Directive rules around classification of medical devices.

Disinfectants are covered by rule 15 of Annex 9, which states “devices designed *specifically* for disinfecting medical devices.....”. The key word here being “specifically”.

So dual labelling as Medical Device & a surface disinfectant is not realistically possible, unless we remove the CE mark from the product. Therefore Virkon is not CE marked. It is marketed for hard surfaces only under the Biocidal Products Directive (BPD).