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Cologne, 22.10.2021

Declaration
Here we confirm that the following products are classified as accessories and not as medical devices:
Accessories:
Opalescence Packet Tray Case Variety Pack SKU 707
Ultralume LED Surface Bracket SKU 1667
Astringedent Spot Remover SKU 2160
Overnight Carry- All Bag SKU 5337
Composite and Cement Dispensing Guns SKU 6345,7800
UltraSeal XT Hydro,Black Light Keychain SKU 35551

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Ultradent website | Opalescence website

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Cologne, 22.10.2021

Declaration:

Here we confirm that the following products are classified as cosmetic products, (notification at the CPNP portal) and not as medical devices.

Tooth Whitening;
Opalescence Go Mint SKU 4634,4639, 4644,4649.
Opalescence Go Melon SKU 3592, 3593, 3599, 3600
Opalescence PF 10% Mint SKU 5364, 5379, 5394.
Opalescence PF 10% Melon SKU 5365, 5380, 5395.
Opalescence PF 10 % Regular/Neutral SKU 5366, 5381, 5396.
Opalescence PF 16% Mint SKU 4480,4483,4486.
Opalescence PF 16% Melon SKU 4481,4484,4487.
Opalescence PF 16% Regular/Neutral SKU 4482,4485,4488.
Toothpastes:
Opalescence Whitening Toothpaste SKU 401,402
Opalescence Whitening Sensitivity Relief Toothpaste SKU 3470,3472

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Classification information

Indications for use:
LC Block-Out Resin is used to create a reservoir for tooth whitening gels during the production of individual trays and may be used in other procedures in the dental laboratory, model and die repairs for example.
Description:
LC Block-Out Resin is a light-cured resin which is neither used on or near patients but only for procedures in the dental laboratory. There is therefore no risk to the patient if this product does not function correctly.
Conclusion:
We hereby certify that LC Block-Out Resin, manufactured by Ultradent Products Inc., located at 505 West Ultradent Drive (10200 South) South Jordan, UT 84095, USA is a dental laboratory item only and is not used on or near patients and so does not fulfil the definition of a Medical Device according to EEC 92I431 (MDD), EU 2017/745(MDR).

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