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SHARING EXPERTISE

To whom it may concern

RE: Aesculap C-Clamp for Unitrac Pneumatic Arm (RT079R) & Interface adapter (RT020R)

Please note that the Aesculap C-Clamp & interface adapter should be machine washed in a thermo washer disinfector compatible to CFPP 01-01 Part D (HTM 2030) recommendations and should be subjected to a cleaning phase of 75 degrees Celsius and a disinfecting phase of between 90 to 95 degrees Celsius.

Chemistries used in this phase should be of a pH between 7.0 to 11.0. Please note, extended exposure to higher pH levels will result in damage to the surface of this device.

Sterilisation should follow CFPP 01-01 Part C (HTM 2010) recommendations and the C-Clamp & interface adapter can be sterilised between 134 to 137 degrees Celsius for a minimum holding time of three minutes to comply with the UK regulations

Aesculap develops and produces medical devices according tot he European medical Device Directive (MDD 93/42/EEC). Our compliance with these regulations is demonstrated by displaying all of our devices with the CE mark, and all products and processes are strictly validated in accordance with MDD 93/44/EEC.

Amongst other things, MDD 93/44/EEC validates cleaning and reprocessing of medical devices, and Aesculap has proven effective reprocessing, with an internal process for every reusable medical device, including the C-Clamp & interface adapter for the Unitrac pneumatic arm.

If reprocessed in line with the above specifications and CFPP (HTM) recommendations, as validated, you can be assured that the C-Clamp & interface adapter will be fully decontaminated and sterile.

Please do not hesitate in contacting me directly should you require any additional information.

Kind Regards

Yours sincerely

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