Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

MHRA
10 South Colonnade
Canary Wharf
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United Kingdom

www.gov.uk/mhra

Ms G Curtis

GMC Consultancy Ltd

3 September 2019

Dear Ms Curtis,

Re: MEDICAL DEVICES REGULATIONS 2017/745: Custom Made Maxillofacial Devices

Further to our useful meeting this morning with yourself and your colleagues from Maxillofacial Units and Sterile Service Departments I can confirm the following, regardless of whether the devices are in house or supplied externally :

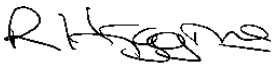
- The General Safety and Performance Requirements (GSPR) which are outlined in Annex I apply.
- The unit manufacturing the device needs to provide their sterilisation subcontractor or final user with any cleaning and sterilisation instructions.
- A Quality System (preferably meeting the requirements of ISO13485) needs to be in place and operating but it does not need to be certified by a 3rd party such as a Notified Body.
- Registration with MHRA is not required.

There was some concern that some sterile service subcontractors would not process such custom made devices which had not been manufactured under a certified quality system. From MHRA's perspective it should be sufficient that a quality system is in place with documented evidence that internal audits are being routinely performed to ensure it's proper implementation and maintenance.

I hope this covers our discussions but please do not hesitate to contact me if you require any further clarification in writing.

Kind regards.

Yours sincerely



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