The use of animal free collagen could significantly lower the development costs of a medical device.

The use of animal free recombinant collagen, rather than collagen extracted from animals, could significantly lower the development costs of a medical device by not contributing to the device regulatory classification so that the device is deemed Class II rather than an automatic Class III.

In the UK, the governmental organisation that assess the compliance of a medical device with the regulatory standard is the Medicines and Healthcare products Regulatory Agency (MHRA). The medical device must comply with the Medical Device Regulations (MDR). Medical devices are classified as Class I, Class II and Class III depending on their clinical application and components. The degree of integration with the human body increases with the number (I to III) and so the regulatory hurdles for the device development and compliance also increase with a significant increase in cost to bring the device to market.

ProColl have had strong guidance that the MHRA would likely identify that our animal free recombinant collagen would not bring the incorporating medical device under Rule 17 UK MDR/EU MDD or Rule 18 EU MDR. The relevant sections of the Medical Devices Regulations 2002 (https://www.legislation.gov.uk/uksi/2002/618/contents/made) which must be followed when developing any medical device; from a wound dressing to a heart valve. The relevant sections of the MDR state the following.

UK MDR 2002 as amended/EU MDD
Rule 17
'All devices manufactured utilizing animal tissues or derivatives rendered non-viable are Class III except where such devices are intended to come into contact with intact skin only.'

EU MDR
Rule 18
'All devices manufactured utilising tissues or cells of human or animal origin, or their derivatives, which are non-viable or rendered non-viable, are classified as class III, unless such devices are manufactured utilising tissues or cells of animal origin, or their derivatives, which are non-viable or rendered non-viable and are devices intended to come into contact with intact skin only.'

Animal free collagen from ProColl is manufactured using recombinant technologies and not utilising animal tissues or cells of an animal origin as stated in the MDR rules which would lead to a class III classification. Multiple classification rules may be applicable to any medical device depending on the characteristics of the device in question, and the strictest rule resulting in the highest risk classification will determine the final risk class of the device. As such, the applicability of all other classification rules would have to be considered to be able to determine the final risk classification of medical devices utilising the recombinant collagen.

Guidance on how to apply the risk classification rules can be found in MEDDEV 2.4/1 rev 9 for UK MDR/EU MDD, and in MDCG guidance document MDCG 2021-24 for EU MDR.

The competent authorities for medical devices in other territories outside the UK may hold diverging views on the appropriate classification of certain medical products. *We would advise you to seek the views of your own professional consultant's expert in the regulation of medical devices. We are simply giving our opinion to help in a strategy for developing a medical device and such views are not meant to be a definitive statement of law.*

Please contact ProColl if you would like to discuss our research into the topic and supply of the different recombinant collagens we manufacture under our ISO 13485 quality management system.