

7<sup>th</sup>. September, 2018

To whom it may concern,

## 1. Surgical Instruments

Most of you are probably aware that as from May 2020 a new law ( MDR ) will apply to the registration of medical products in Europe. This is a law and not just a guideline. There will be a new class of medical products – reusable surgical instruments. Needless to say the amount of efforts and resources required to register surgical instruments in the future is considerably more than was the case in the past. The purpose of this is to inform you of the changes taking place. How does this affect you our customer ?

- Most of our instruments are manufactured in the Tuttlingen area in Southern Germany. Whilst there are several large companies in Tuttlingen most of the manufacturing takes place in small to medium sized businesses. Even the large companies such as Karl Storz and Aesculap do not manufacture many of their products themselves. Whilst many of these manufacturers have excellent quality they do not always have adequate internal quality systems of a high enough standard to meet the new requirements. This means that some of these companies are being sold and some are closing down completely.

This has meant that we have in several cases had to switch all production from one supplier to one or more other suppliers, the logistics of which have not been easy. Remember we are talking here about high quality surgical instruments with a high portion of skilled manual work. Also remember that this is not straight forward as for many special instruments there are only one or two manufacturers in the whole of Tuttlingen. This is an ongoing process and there are continuous changes taking place.

- The costs in future for German Quality Medical Products will rise. In the case of instruments one of the new requirements is to have a UDI code lasered on

to the body of the instrument. For an instrument with a high initial cost, the extra costs can be absorbed but for low cost instruments the extra costs now make up a material part of the total costs. This will lead to price increases.

- This will definitely reduce in future for companies selling instruments with CE marks.

Sincerely,

A handwritten signature in blue ink that reads "David Spiggle". The signature is written in a cursive style with a long horizontal line extending from the end of the name.

David Spiggle