

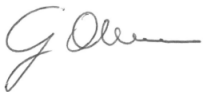
11-FEB-2022

To Whom It May Concern:

This letter will serve to attest to the fact that part nr. DS-5501-189 is a kit. A kit is defined as a collection of medical devices, packaged together for sales/convenience purposes only. The kit is not CE Marked and it is not considered as system or procedural kit as defined in article 22 of MDR. Therefore, the kit part number will not show on a Declaration of Conformity.

Part nr. DS-5501-189 consists of two (2) medical devices: part nr. DS-5501-300 and REUSE-11. The specific medical devices are individually CE Marked.

Sincerely,



Giovanni Ottaviano
EMEA Regulatory Affairs Specialist
Mortara Instrument Europe s.r.l.