DQS Medizinprodukte GmbH | August-Schanz-Str. 21 | 60433 Frankfurt am Main

REDA Instrumente GmbH
Gänsäcker 34
78532 Tuttlingen

Frankfurt a. M. 05.05.2023

Confirmation letter to certification under Directive 93/42/EEC (certification holder: REDA Instrumente GmbH; certificate registration no.: 070894 MR2; ID: 170742825; effective date: 2019-03-18; expiry date: 2023-05-07)

To whom it may concern,

This letter confirms that:

- The certificate referred to above was issued by DQS Medizinprodukte GmbH under the requirements of the Medical Device Directive (93/42/EEC) (the "MDD"); and
- the certificate referred to covers the legacy device(s) specified below, (or covered the legacy devices at the time of its expiry); and
- the certificate referred to above has either expired by course of time (and was valid at the date of its expiry, it neither having been suspended nor withdrawn), or is to expire shortly (and remains valid at the date of this letter); and
- an application under the MDR for the devices specified below has been accepted and the contract with the manufacturer signed for devices specified below.

This letter is limited to covering following devices:

- Monopolary and bipolary instruments for HF-surgery (UMDNS: 16-860, 11-494, 11-497, 16-206): Application MDR accepted on 2022-12-12 (MDA 0312)
- Endoscopic and laparoscopic devices and accessories (UMDNS: 11-274, 12-291): Application MDR accepted on 2022-12-12 (MDN 1208)
- Traumological implants (bone wires; UMDNS: 16-104): Application MDR accepted on 2022-12-12 (MDN 1102)
- Endoscopic suction tubes and accessories: Application MDR accepted on 2022-12-12 (MDA 0312)

Yours sincerely,

p.p.

DQS Medizinprodukte GmbH