

FIELD SAFETY NOTICE (FSN)

Telefunken and HeartReset HR1 & FA1

Concerning:

Products sold with invalid CE Certificate

Date	October 16 th 2019
Sender	GGT Holding B.V. Newtonweg 10 5928 PN Venlo The Netherlands
Addressee	Users of the mentioned AED's sold after July 18 th 2016

Description of the problem including the identified cause:

The appointed notified body provided a falsified CE Certificate. Previously the products were certified by another notified body (1023)

Cause of the malfunction:

no malfunction was found. No design changes took place after the certificate became invalid.

Risk for Patients or Users of the device:

Devices work according the manual and ICOR guidelines

Assessment of the risk:

None

What measures should be taken by the addressee:

Make sure that green led is blinking as proof that the daily self-test was passed

Corrective action:

re)-certification of the concerned products without a valid CE - certificate. All end users of the concerned defibrillators are known and can be informed about corrective actions accordingly. According agreements for (re)-certification have already been made with a notified body and the technical supporting company in order to finalize this within the coming 3-4 months.

Inquiries: info@DefiTeq.com