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SCHILLER
MEDICAL

FRED PA-1 and DEFISIGN durability under the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices

Context :
Key dates:

- _ Adoption: 5 April 2017: the text has been approved by the European Parliament.
- _ Application: May 26, 2017.
- _ Implementation: May 26, 2020

Certificates issued prior to this date, based on the current Directive 93/42 / EC, will be valid until they expire, but not beyond 27 May 2024.

Current situation :
Notified Bodies have applied for notification under the new regulation.
No Notified Body has been designated to date. No Medical Device Manufacturer can claim compliance with Regulation 2017/745 / EC
Current classification of the PA-1/DefiSign according to EU legislation is Class IIb
Future classification of the PA-1/DefiSign will be Class III,
We currently comply to Class IV within our regulatory status with the Canadian authorities

Planification of SCHILLER Médical for FRED PA-1 and DEFISIGN :
Our Notified Body is GMED.
GMED has applied for notification as a Notified Body for the 2017/745 / EC Regulation.
Until the CE certification under the new Directive, SCHILLER Medical continues to maintain the CE marking certificates according to the Directive in application 93/42 / EC.
After May 26, 2020, FRED PA-1 and DEFISIGN will be part of the Medical Devices concerned by the transition to Regulation 2017/745 / EC.
The Regulatory Affairs Department of SCHILLER Medical is preparing this transition, in compliance with the forthcoming Regulations, and will present to the GMED the FRED PA-1 and DEFISIGN Technical files, in accordance with the rules of the Class III Devices (Europe).

Wissembourg, december 4th, 2018

Alain Weissinger
Quality and Regulatory Affairs Director