EPRISE ROAD SHOW
Nov 2018

SPID™: a versatile diagnositc platform

Single use patented sensor

Proprietary scoring algorithm

Compact plateform

NASHMIR:
NASH Diagnostic

SYNOFAST:
Septic Arthritis Diagnostic

OEM:
Quality control

DIAFIR
Innovative Diagnostic Solutions

Regulatory environment

IN VITRO DIAGNOSTIC DEVICE

- 98/79/CE
- ISO 13485
- ISO 14971
- ISO 61010-1
- NF EN 62366
- ISO 62304
- ISO 15223 - 1

DIAFIR Innovative Diagnostic Solutions

Early QA and regulatory implementation

Pros

- ✓ structure the organization
- ✓ More comprehensive risk analysis
- ✓ Image for stakeholders

Cons

- ☒ Clinical trial approval process
- ☒ Standard frequents changes
  with a trend opposite to general QA management one toward simplification

DIAFIR Innovative Diagnostic Solutions

Challenges to come

New regulation 2017/746

Longer time to market

✓ Clinical trials OK

⚠ Find a notified body

⚠ Adaptation to new auditor

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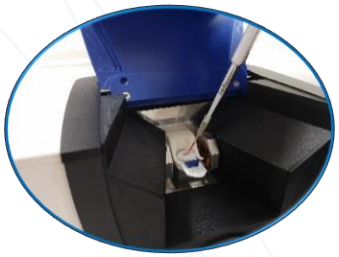

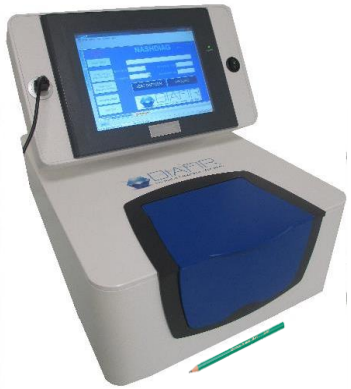

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