

**Camgenium's Foundation 2a platform is a pre-validated regulatory compliant software infrastructure for MedTech innovators to build class IIa / IIb medical devices.**

This next-generation medical firmware seamlessly provides the necessary foundation layer for building any compliant class IIa / IIb medical device. Camgenium provides the toolkit to empower MedTech innovators to develop new classes of medical devices. Meeting the security requirements of multiple standards necessary for class IIa / IIb device is complex and requires a deep understanding of embedded and platform security. The use of Foundation 2a frees development engineers to concentrate on their specific applications.

## Product overview

Camgenium's advanced medical firmware provides the required foundation layer for building any compliant class IIa / IIb medical device. Camgenium has over 17 years of expertise in building regulatory compliant medical devices for its clients. Camgenium's Foundation 2a platform minimises risk, accelerates development time, and reduces cost with its critical care medical device standard, compliant software.

The platform provides the base layer of compliant firmware, technical file preparation and submission to enable the development of any medical device up to class IIa / IIb. Camgenium can manage all regulatory responsibilities from technical file preparation and submission, to EU MDR 2017/745 compliance documentation, monitoring, and surveillance.

Depending on the complexity of the product the use of the Foundation 2a firmware and platform can save years of development time and avoid the need to recruit multiple expert staff in diverse fields. Camgenium can provide a full service offering to realise new medical technologies.



100% compliance against all applicable security standards



Management of EU MDR 2017/745 compliance documentation



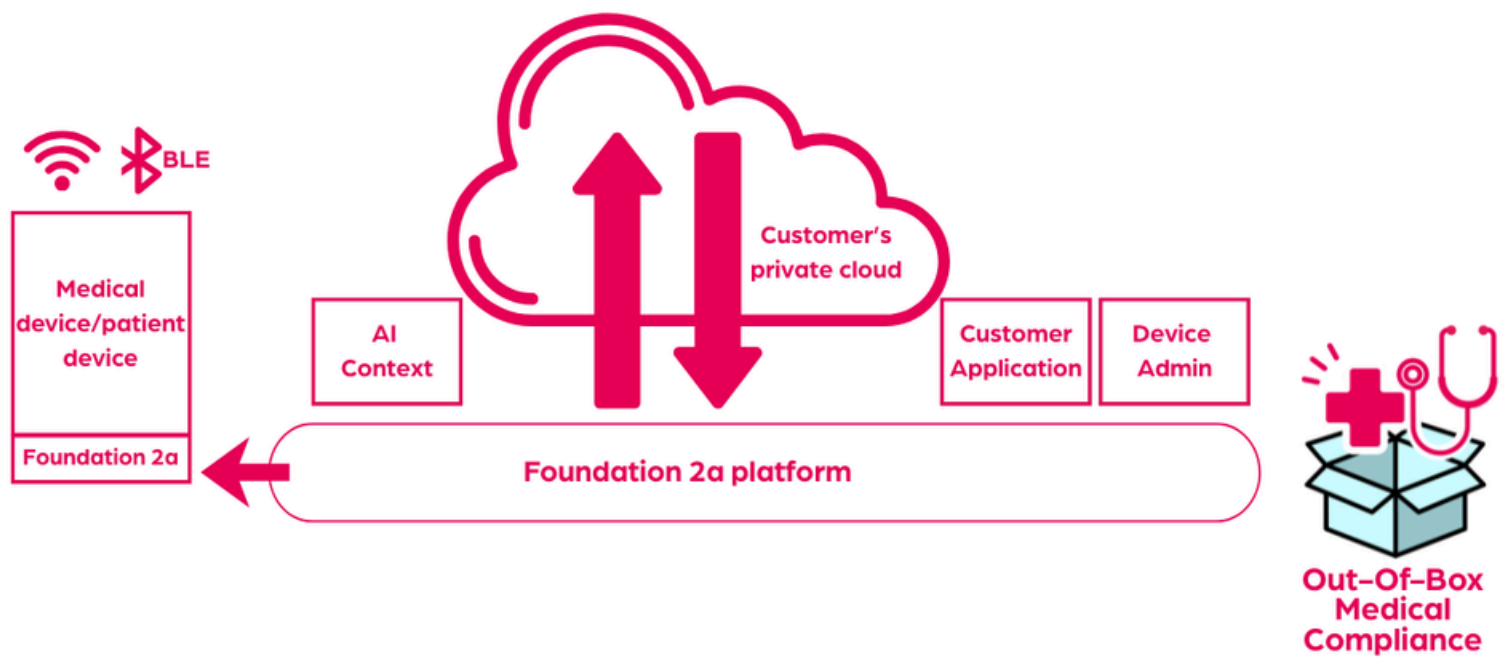
Pre-validated medical device software infrastructure rapidly reduces development time and cost



**Out-Of-Box  
Medical  
Compliance**

**Get in touch with our experts**





Medical devices built on Camgenium's Foundation 2a layer will meet 100% compliance against all applicable security standards. The pre-existing medical firmware and cloud platform developed by Camgenium eliminates months of development and validation time. This allows our expert team of engineers to build new medical devices significantly faster compared to other service providers starting the development from scratch. Foundation 2a is supported by full documentation evidence meeting the necessary medical device development requirements. Innovators who use the Foundation 2a platform dramatically accelerate and de-risk connected medical device development.

Camgenium has deep regulatory knowledge, its software services are certified to the NHS Data Security and Protection Toolkit, HIPAA, ISO 27001, ISO 13485 standards and is GDPR ready. All data handling strictly adheres to local healthcare regulations, ensuring the highest standards of patient privacy and legal compliance.

## Foundation 2a

## Standards



**IEC 62304:2006  
+AMD1:2015  
(Class B)**



**IEC 81001-5-1:2021  
Cybersecurity**



**FDA Cybersecurity  
Guidance (2023)**



**EU MDR 2017/745  
(Annex I)**



**ISO 14971:2019  
Risk Management**



**Approved**

**Get in touch with our experts**

**Camgenium**

[contact@camgenium.com](mailto:contact@camgenium.com)

[www.camgenium.com](http://www.camgenium.com)

2a Oakington Business Park, Cambridge, CB24 3DQ, UK