

Medical Device Regulation

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Medical Devices and Legislation Unit

- Medical device legislation and regulations
 - *Regulation is reserved and under the UK MHRA*
- Medical devices policy.
 - *Health is devolved*
- Medical devices supply.
 - *Usually UK wide but may have different impacts in each of the 4 nations*
- Medical device strategy

Medical Devices

- 2 million medical devices
- Widely used in care pathways
- 1 in 10 have an implantable device
- Highly innovative
- Relatively low barrier to market entry
- Performance vs outcomes



Cumberledge Report: First Do No Harm

Rec 7: Central database linking patients to devices and linking to registers



NHS Scotland Scan For Safety

2022
NSS led delivery
Medical devices and
Equipment



UK MDIS

Outcome Registries



2016

2020

2021

2022

2023

2024

2025

EU Exit

Medicines & Medical Devices Act

Framework Legislation
Clause 19 formation of UK MDIS



UK Medical Device Regulations

July 2024
Manufacturers must provide UDI
Health providers must store UDI
for Class III and IIb devices



```
@Link
@package _5
*/
if ( ! function_exists( 'incode_starter_setup' ) )
/**
 * Sets up theme defaults and registers support for various
 * Note that this function is hooked into the after_setup_theme
 * runs before the init hook. The init hook is too late for
 * as indicating support for post thumbnails.
 */
function incode_starter_setup() {
/*
 * Make theme available for translation.
 * Translations can be filed in the /languages/ directory.
 * If you're building a theme based on incode_starter, you can
 * change the domain of the theme by looking at the theme
 * text domain and introducing the same text domain to your
 * theme.
 */
load_theme_textdomain( 'incode_starter', get_template_directory() . '/languages' );
}
}

```

- Improving medical device data
- Software as a medical device
- In house device manufacture
- Post market surveillance

New Medical Device Regulation



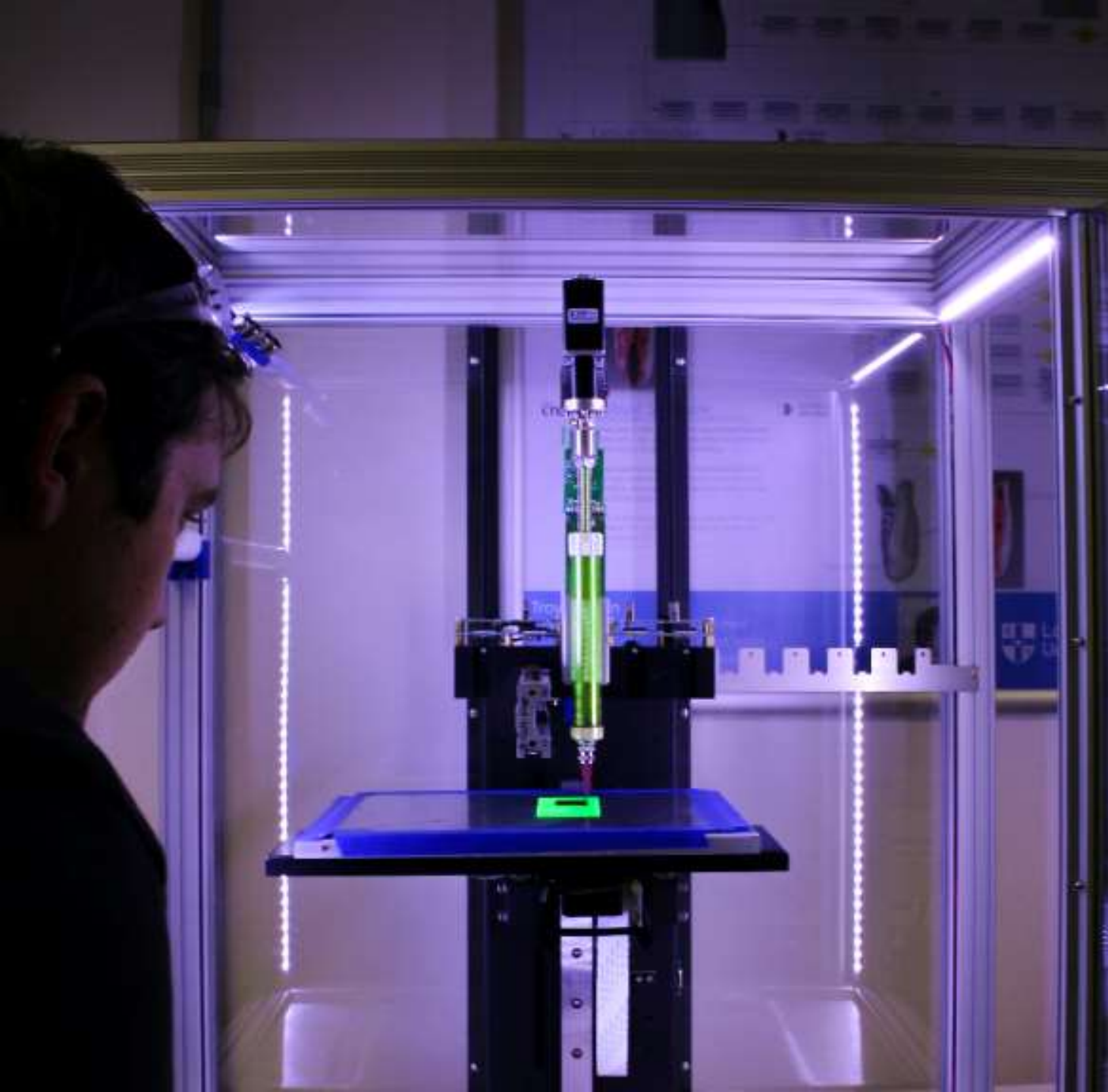
Improving medical device data

- Unique device identifiers
 - Enables traceability and data linkage
 - Requires manufacturers to apply UDI
 - Requires healthcare providers to store UDI for implantable devices
 - >>>> NHS Scotland Scan For Safety Programme
- Post-market surveillance
 - Strengthen safety and performance data
 - Significantly increased requirements ; serious incidents, data from registries, scientific literature
 - Some improvement in transparency for highest risk devices



SAMD & AI : a medical device

- 80% currently Class I
- Move to up – classification
- Multiple work programmes
- Digital Clinical Safety
- Significant skill gap



In house manufacturing

- Many healthcare providers are effectively manufacturers
- At present Health Institute Exemption
- New UK MDR requirements
 - to register the device with MHRA
 - to have a quality management system (though not certified)
 - to retain a technical document file
 - to make provisions for adverse incident reporting
 - do not require CE

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