

# SciPharm

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SciPharm





Remote Monitoring  
and Programming of  
Medical Devices



Mobile/Laptop  
Access Pro



Mobile Access  
@ Home

MedCon Management Platform

SciPharm

- **Developed according to ISO 13485**
- **For a wide range of Medical Devices**
- **MDR and GDPR ready**
- **State-of-the-art authentication**
- **End-to-end encrypted**

# MedCon System: who does what ?



## IIP

Legal Manufacturer  
= **Tricumed (D)**  
Critical Supplier =  
Various

## CommsUnit

Legal Manufacturer  
= **SciPharm (L)**  
Critical Supplier =  
= **Tuomi (L)**

## MobileApp

Legal Manufacturer  
= **SciPharm (L)**  
Critical Supplier =  
= **Tuomi (L)**

## Control Application

Legal Manufacturer  
= **SciPharm (L)**  
Critical Supplier =  
= **Tuomi (L)**

## MedCon System: Regulatory Strategy

Each device shall have its own CE certification,  
but this certification can only be done with all 4 together.

Device Classification of the MD, CommsUnit, MobileApp  
and Control Application according to MDR.

	CommsUnit	MobileApp	Control Application	Implantable Infusion Pump
Class IIa	X (Rule 12)	X (Rule 11)		
Class IIb				
Class III			X (Rule 9)	X

## Regulatory challenges

- **Two legal manufacturers, one system**

# MedCon Management Platform: CommsUnit + MobileApp + Control Application



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Various

**CommsUnit**  
Legal Manufacturer  
= **SciPharm (L)**  
Critical Supplier =  
= **Tuomi (L)**

**MobileApp**  
Legal Manufacturer  
= **SciPharm (L)**  
Critical Supplier =  
= **Tuomi (L)**

**Control Application**  
Legal Manufacturer  
= **SciPharm (L)**  
Critical Supplier =  
= **Tuomi (L)**

# MedCon System: all 4 components: IIP + MedCon Management Platform



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Critical Supplier =  
Various

**CommsUnit**  
Legal Manufacturer  
= **SciPharm (L)**  
Critical Supplier =  
= **Tuomi (L)**

**MobileApp**  
Legal Manufacturer  
= **SciPharm (L)**  
Critical Supplier =  
= **Tuomi (L)**

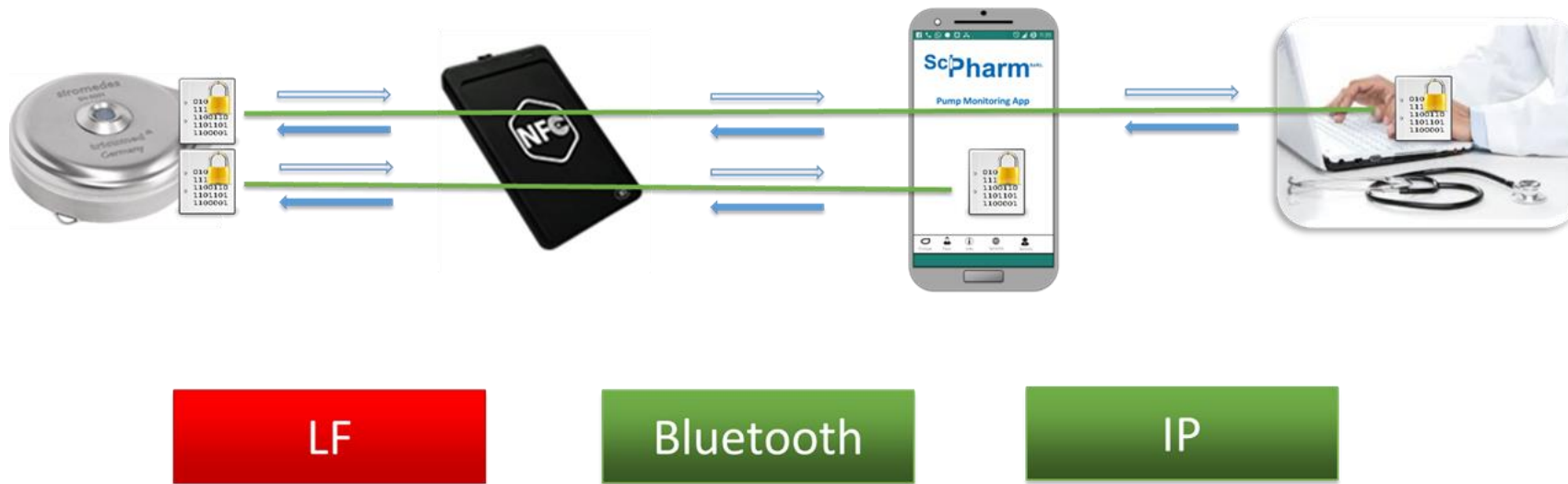
**Control Application**  
Legal Manufacturer  
= **SciPharm (L)**  
Critical Supplier =  
= **Tuomi (L)**



## Regulatory challenges

- Two legal manufacturers, one system
- **Various frequencies and communication protocols**

# MedCon System



## Regulatory challenges

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- **High Software content**

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- **MDD to MDR transition**

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- Various frequencies and communication protocols
- High Software content
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- **No Notified Body in Luxembourg**

## Regulatory challenges

- Two legal manufacturers, one system
- Various frequencies and communication protocols
- High Software content
- MDD to MDR transition
- No Notified Body in Luxembourg
- **Limited consultancy offering in Luxembourg**

**Thank you**

**SciPharm**