

## Bulletin – Transformation to MDR

Lund - Sweden, 2021-05-26

### Summary

As of today, May 26th the Medical Device Regulations goes into effect in the European market. Distributed Medical with our VidiView product follows this transition and products released from this date and onward will all be MDR compliant.



### The MDR product structure

With the transition to MDR we also start seeing the product as a whole. This means that we will, from now on, treat VidiView as one product, consisting of different modules. This view is built upon the fact that the individual parts cannot be used individually but has to be interconnected in an eco-system to function.

We will from this date onwards refer to the product as **VidiView Enterprise Imaging**. This name will cover all of the modules of the system as a whole. Initially the product VidiView Enterprise Imaging will consist of the below parts.

Product UDI	Product Description	Risk class	GMDN
(01)07300009077984(240)1(8012)y.y	VidiView Enterprise Imaging - Server module	MDR, Class I	60724
(01)07300009077984(240)2(8012)y.y	VidiView Enterprise Imaging - Client module	MDR, Class I	60724
(01)07300009077984(240)3(8012)y.y	VidiView Enterprise Imaging - Web Client module	MDR, Class I	60724
(01)07300009077984(240)4(8012)y.y	VidiView Enterprise Imaging - Controller module	MDR, Class I	60724
(01)07300009077984(240)5(8012)y.y	VidiView Enterprise Imaging - Capture module (iOS)	MDR, Class I	60724
(01)07300009077984(240)6(8012)y.y	VidiView Enterprise Imaging - Capture module (Android)	MDR, Class I	60724

1. Table of product modules in the MDR release model

### The initial MDR release

The first release of the product that has undergone the scrutiny of the MDR process within the company will be version 4.9. This means it has been validated and examined in accordance with the new;

- Risk management process
- Requirement management process
- Test scheme and validation process
- Documentation process
- Release process

And later on, the new;

- Post-market surveillance process

The release date of this version will be during Q3 2021.

#### The old MDD versions of VidiView

All old versions of the system, released prior to May 26<sup>th</sup> 2021 will continue to exist, function as before, be used and be serviced in accordance with prior support and service commitments.

We will issue patches for severe IT-security flaws, if such were to be found in legacy products. No feature development nor improvements, what so ever, will be done in any version prior version 4.9.

If and when possible, we suggest all customer upgrade their systems to a MDR compliant release.

We hope all current customers see this transition as a proof of our commitment of delivering the best possible, most secure and safe, medical image management solution available on the market as of today!



Ideon Researchpark, Beta 1  
S-223 70 Lund  
Sweden

Tel +46-755-55 1200  
<http://www.distributedmedical.com>  
[info@distributedmedical.com](mailto:info@distributedmedical.com)