HEXACATH Obtains one of the World first MDR certification for a Class III Coronary Stent Medical Device.

HEXACATH is proud to announce the certification of its TITAN OPTIMAX (bioactive coronary stent coated with Titanium-Nitride-Oxide) according to the New European Regulation (EU) 2017/745 for CE marking.

Coronary stents belong to class III medical devices which holds the highest risk to the patient and/or user according to MDR (Medical Device Regulation) and which is therefore the most difficult to obtain.

We are thrilled TITAN OPTIMAX is among the first coronary stents in the world to be MDR certified, this certification is a true achievement and embodies the commitment of the whole HEXACATH workforce towards Quality, Safety and Performances of its cardiovascular products.

One of the main differences with the former European regulation (MDD) comes from the fact that medical devices manufacturers must document the clinical safety and performances of their devices much more extensively.

At HEXACATH, huge and long term efforts have been made to gather clinical data over more than 10 years to demonstrate the efficacy and safety of the TiTAN OPTiMAX in the most complex indications of angioplasty (Acute Coronary Syndrome or myocardial infarction). We are delighted these efforts have been taken into consideration in the process to obtain the highest level of device approval in the world.

HEXACATH
PIONEER IN BIO ACTIVE COATING

TiTAN OPTiMAX
Bioactive Stent *Made in France*