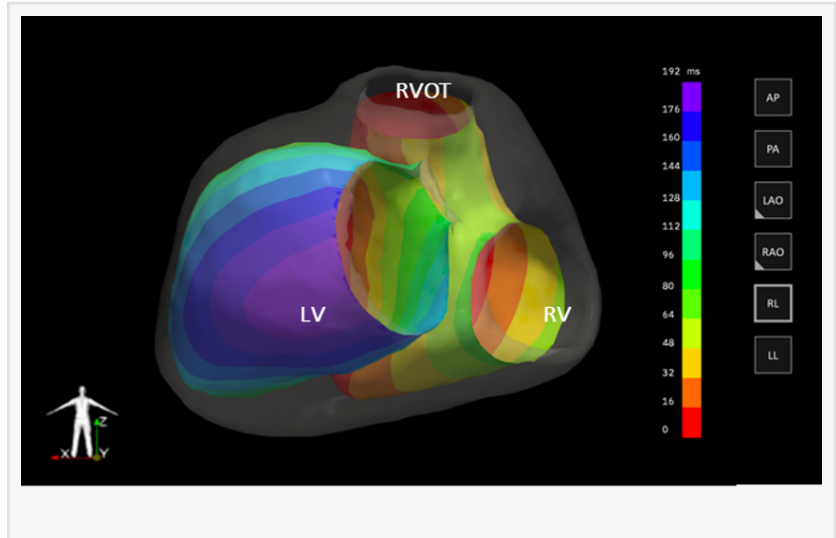


# XSpline SPA Achieves MDR Certification for N.I.C.E., its AI-Powered Cardiac Mapping Software

*XSpline's AI-powered cardiac mapping tool, N.I.C.E., earns EU MDR Class IIb certification, enabling European rollout and advancing CRT treatment outcomes.*

BOLZANO, ITALY, May 14, 2025 /EINPresswire.com/ -- XSpline SPA, a leader in non-invasive cardiac mapping solutions, is proud to announce that its flagship product, N.I.C.E. (Non-Invasive Cardiac Electrophysiology), has received MDR certification as a Class IIb medical device under the European Medical Device Regulation (EU 2017/745).



This certification marks a critical regulatory milestone, confirming the safety and performance of N.I.C.E. and enabling its commercial deployment across European markets. N.I.C.E. is the first real-time, AI-powered software platform for epi- and endocardial electroanatomical mapping based on standard 12-lead ECG and cardiac imaging, significantly reducing CRT (Cardiac Resynchronization Therapy) non-response rates.

By leveraging advanced deep learning algorithms, N.I.C.E. automatically segments cardiac structures, tracks coronary sinus branches, and identifies optimal LV lead placement zones—improving procedural success and patient outcomes. The platform also enables ongoing monitoring during post-procedure follow-up.

“The MDR certification confirms the safety and clinical value of our solution. It paves the way for the commercialization of N.I.C.E. in Europe, starting with our strategic partners in Italy and expanding across the continent,” said Werner Rainer, CEO of XSpline. “This is a pivotal moment not only for our company, but for the field of cardiac electrophysiology.”

XSpline will begin commercial rollout in Q4 2025 and anticipates FDA clearance by the end of the year. With over 250 patients enrolled in clinical trials and a growing body of scientific validation,

N.I.C.E. is set to become a new standard in CRT planning.

Claudia Amatruda  
XSpline SPA  
+39 0471200372  
info@xspline.com

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