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BP+ CE Certificate Extension

The BP+ (BPPLUS-R7) device CE Certificate has received extension of validity under the EU regulations transition rules.

The current CE Certificate expired on 2024-05-26.

The CE Certificate number is G1 083116 0014 and is issued by TUV SUD.

EU Medical Device Regulation (MDR) is a mandatory regulation change that will govern how medical devices are sold in the EU and other markets that leverage the CE Mark.

EU MDR replaces the Medical Device Directive (MDD). Products that were previously MDD certified require reassessment to comply with EU MDR and achieve certification or CE Marking.

Under the current European regulations Notified Bodies, such as TUV, are not permitted to issue further MDD CE Certificates.

The EU MDR 2nd Amendment Regulation (EU) 2023/607 extends the transition period (until end of 2028), via the extension of the validity of legacy MDD CE Certificates.

This regulation states that MDD Devices compliantly placed on the market and fulfilling the EU MDR 2nd amendment conditions may continue to be sold until they reach the expiration date of 2028-12-31.

The BP+ device meets the conditions of this regulation.

The attached extension of validity letter extends the validity of the BP+ CE Certificate G2 083116 0014 until 2028-12-31.

Nick Schicht
Uscom Limited

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