EC - DECLARATION OF CONFORMITY

We,
PLASMACURE B.V.
Transistorweg 5
6534 AT Nijmegen
The Netherlands

Declare under our responsibility that the PLASOMA System:

PLASOMA Pulser (PU01)
PLASOMA Pad (C0801)

To which this declaration relates, is in conformity with the following (harmonized) standards:

EN ISO10993-1:2009+AC:2010	EN 62366:2008	EN ISO 11607-1:2009
EN ISO14971:2012	EN-ISO 14155:2011	EN ISO 11607-2:2006
EN1041:2008	EN-ISO 15233-1:2016	EN ISO 11137-1:2015
EN ISO 11137-2:2015	EN ISO 13485:2016	EN 60601-1-2:2015
EN 60601-2-57:2011	EN 60601-1-8:2007	EN 62304:2006+AC:2008
EN-60601-1:2006+AC:2010+A1:2013		

following the provisions of:

the Medical Device Directive 93/42/EEC,

and are produced under a quality scheme in conformity with EN ISO13485:2016.

The PLASOMA System is compliant to 93/42/EEC annex I.

The Notified Body: ECM 1282 performed an MDD Annex II (- section 4) CE certification
and issued the certificate number ECM20MDD009 rev 0.

Remarks:

This Declaration of Conformity relates to the PLASOMA Pulser, with type number PU01 and uniquely identified with serial numbers from SN 20201100 forward, and the PLASOMA Pad (C0801), uniquely identified by batch number starting from 0125027 onwards.
The PLASOMA System is a class IIb medical device according rule 4 of Annex IX of the MDD.

Nijmegen, the Netherlands. September 2020

Bas Zeper,
CEO Plasmacure B.V.

Signature: