EC - DECLARATION OF CONFORMITY

We, PHLECS B.V
High Tech Campus 12 5656 AE
EINDHOVEN, the Netherlands.

Declare under our responsibility that the product

PHLECS Full Body Blue: (Treatment: Symptom relief of Psoriasis Vulgaris)

FBB-GEN1.0

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

EN60601-1:2006/A1:2013	EN 1041:2008
EN60601-1-2:2015	EN 62366:2008
EN ISO14971:2012	EN 60601-1-6:2010

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 Notified Body: DEKRA 0344 performed a MDD Annex V CE certification
and issued the certificate number 2238613CE01.

Remarks:

This Declaration of Conformity relates to the Full Body Blue (FBB) device, with type number FBB-GEN1.0 and uniquely identified with serial numbers from SN: A100000119 onwards.
The Full Body Blue device is a class IIa medical device according rule 9 of Annex IX of the MDD.

Eindhoven, Netherlands. 08 November 2020

David Aubert
CEO,
PHLECS B.V.

Signature: