PlantTec Medical

MEDICAL SOLUTIONS INSPIRED BY NATURE

EC Declaration of Conformity

Document number: DoC 9.2-4-17 Revision level: 3.2 Date: 22.01.2021

PRODUCT IDENTIFICATION	
Product title:	**Reference number(s):**
4DFLap™ (4DryField® PH applicator)	LA0014-EU LA0038-EU

MANUFACTURER	
Name of company:	**Address of company:**
PlantTec Medical GmbH	Bleckeder Landstraße 22 21337 Lüneburg Germany

REGISTRATION INFORMATION		
Notified Body with ID number:	**Address of Notified Body:**	**CE certificate number:**
MEDCERT GmbH CE 0482	Pilatuspool 2 20355 Hamburg Germany	7272GB410201120A

CONFORMITY ASSESSMENT		
Device classification:	**Route to compliance:**	**Standards applied:**
Class IIa Rule 6	Annex IX, Section 2.2. of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices	The list of applicable standards is reported at separate document # 17.5-3

The **PlantTec Medical GmbH** declares with sole responsibility that the medical devices 4DFLap™ (4DryField® PH applicator) comply with the essential requirements according to Annex I of the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (with all amendments). The conformity evaluation was performed according to Annex II of the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices. This declaration is valid until issuing of a revision due to changing the medical devices and/or nearest expiration of a CE certificate on 27.05.2024.

COMPANY REPRESENTATIVE: Prof. Dr. Joachim Laas

JOB TITLE: Managing Director

SIGNATURE: Dr. Joachim Laas **DATE:** 22.01.2021

PlantTec Medical

MEDICAL SOLUTIONS INSPIRED BY NATURE

EC Declaration of Conformity

Document number: DoC 9.2-4-13 Revision level: 7.0 Date: 22.01.2021

PRODUCT IDENTIFICATION			
Product title:	**Reference number(s):**		
4DryField® PH (provides hemostasis – prevents adhesions)	SK0100-EU SK0250-EU SK0500-EU SK0001-EU SK0003-EU SK0005-EU SK0009-EU DK0001-EU	SK0100-AM SK0250-AM SK0500-AM SK0001-AM SK0003-AM SK0005-AM SK0009-AM	SK0100-AS SK0250-AS SK0500-AS SK0001-AS SK0003-AS SK0005-AS SK0009-AS

MANUFACTURER	
Name of company:	**Address of company:**
PlantTec Medical GmbH	Bleckeder Landstraße 22 21337 Lüneburg Germany

REGISTRATION INFORMATION		
Notified Body with ID number:	**Address of Notified Body:**	**CE certificate number:**
MEDCERT GmbH CE 0482	Pilatuspool 2 20355 Hamburg Germany	7272GB410201120A 13370GB411210122A

CONFORMITY ASSESSMENT		
Device classification:	**Route to compliance:**	**Standards applied:**
Class III Rule 7	Annex IX, Section 2.3. of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices	The list of applicable standards is reported at separate document # 13.5-3.

The **PlantTec Medical GmbH** declares with sole responsibility that the medical devices 4DryField® PH (provides hemostasis – prevents adhesions) comply with the essential requirements according to Annex I of the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (with all amendments). The conformity evaluation was performed according to Annex II of the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices. This declaration is valid until issuing of a revision due to changing the medical devices and/or nearest expiration of a CE certificate on 27.05.2024.

COMPANY REPRESENTATIVE: Prof. Dr. Joachim Laas

JOB TITLE: Managing Director

SIGNATURE: ..... **DATE:** 22.01.2021