Deklaracja Zgodności WE

EC Declaration of Conformity

Firma:
Company **LANGSTEINER Sp. z o.o**

Adres:
Adress **Mników 405**
32-084 Morawica
Polska / Poland

SRN: PL-MF-000010968

Deklaruje z pełną odpowiedzialnością, że wyrób:
Declare with sole responsibility, that our product of kind:

Nazwa wyrobu: Plastry na odciski z kwasem salicylowym
Adhesive plasters for corn treatment with salicylic acid

Wersje: **Plastry do usuwania odcisków z kwasem salicylowym**
(Corn removal plasters with salicylic acid,
Apósitos Callicidas con ácido salicílico,
Cerotti callifughi con acido salicilico,
Pensos Calicidas com ácido salicílico,
Plaster zur entferung von Hühneraugen mit Salicylsäure,
Pansements pour cors avec acide salicylique,
ΕΠΙΘΕΜΑΤΑ ΑΦΑΙΡΕΣΗΣ ΚΑΛΩΝ Περιεχει σαλικυλικο οξυ,
Likdoorn verwijder pleisters met Salicylzuur,
Náplasti na odstraňování kuřích ok s kyselinou salicylovou,
Salisilik Asitli Nasir Bandi)

Kod Basic UDI-DI: 590144825CORNPLASTERDN

jest zgodny z mającymi zastosowanie wymaganiami Dyrektywy Europejskiej 93/42/EEC jak i Ustawy **o wyrobach medycznych z dnia 20.05.2010 ze zmianami oraz Rozporządzeniami Ministra Zdrowia i został sklasyfikowany do klasy III zgodnie z regułą 13**

complies with the applicable requirements of European Directive 93/42/EEC and the polish Medical Devices Act of 20.05.2010 as amended and regulations of the Minister of Health and has been classified in Class III in accordance with Rule 13

Procedurę oceny zgodności przeprowadzono wg załącznika II MDD 93/42/EEC, Pełny system jakości.

The conformity assessment procedure has been carried out according to annex II of Medical Device Directive 93/42/EEC - Full quality system.

W ocenie zgodności brała udział Jednostka Notyfikowana nr 2274 TÜV Nord Polska Sp. z o.o. ul. Mickiewicza 29, 40-085 Katowice

In assessing has participated the Notified Body no. 2274 TÜV Nord Polska Sp. z o.o. ul. Mickiewicza 29, 40-085 Katowice

CE 2274

Producent zapewnił zgodność z wymaganiami Art 120 p.3 z MDR 2017/745.

The manufacturer has ensured compliance with the requirements of Art 120 p.3 of MDR 2017/745.

Wyrób spełnia wymagania następujących norm zharmonizowanych: EN ISO 13485, EN ISO 14971, EN ISO 20417, EN ISO 15223, EN ISO 10993

Device meet requirements following harmonized standards: EN ISO 13485, EN ISO 14971, EN 20417, EN ISO 15223, EN ISO 10993

Kraków, 22.10.2021

Zatwierdziła: Alicja Langsteiner

TÜVNORD

Katowice, 28 lutego 2024

TÜV NORD Polska Sp. z o.o
ul. Mickiewicza 29
40-085 Katowice
Poland

Notified Body Confirmation Letter
Reference: 2/24

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, TUV NORD Polska Sp. z o.o. , a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 2274 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Langsteiner
PHARMACEUTICAL

Langsteiner Sp.z o.o.
Mników 405 Street
32–084 Morawica City
Poland

SRN PL-MF-000010968

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 31 December 2027 for Class III devices

DLA NASZEJ WSPÓLNEJ PRZYSZŁOŚCI TÜV NORD POLSKA PROWADZI NASADZENIA NOWYCH DRZEW I UŻYWA PAPIERU BIUROWEGO Z RECYKLINGU.

TÜVNORD

On behalf of the Notified Body,

Jowita Dyrda
Deputy Head of the Notifed Body No. 2274 for Medical Devices
TÜV NORD Polska Sp. z o.o.

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Plastry na odciski z kwasem salicylowym – **Adhesive plasters for corn treatment with salicylic acid –** **Basic UDI-DI : 590144825CORNPLASTERDN**	Class III	'N/A'	TNP/MDD/0321/3906/2020

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/02/28	Version 1	Initial issue

TÜV NORD Polska Sp. z o. o.
ul. Mickiewicza 29
40-085 Katowice
tel.: +48 32 786 46 46
biuro@tuv-nord.pl
www.tuv-nord.pl

Zarząd:
Dagmara Żygowska - Prezes Zarządu

NIP 634-10-14-590
REGON: 272557766
Sąd Rejonowy w Katowicach, KRS: 0000118633
Kapitał zakładowy: 850000 PLN

Konto bankowe:
mBank o. korporacyjny Katowice
02 1140 1078 0000 4042 4600 1001
EUR 72 1140 1078 0000 4042 4600 1002
USD 93 1140 1078 0000 4042 4600 1012