POHL BOSKAMP

## Konformitätserklärung

Wir, Firma
G. Pohl-Boskamp GmbH & Co. KG
Kieler Strasse 11
25551 Hohenlockstedt
Deutschland

erklären in eigener Verantwortung, dass das Medizinprodukt der Risikoklasse I (Regel 5, Spiegelstrich 2 des Anhangs IX der u. g. Richtlinie)

**GeloTonsil® Gurgelgel**
Rezepturcodierung: 585

auf das sich diese Erklärung bezieht, den Anforderungen des

Anhang I

und dem Konformitätsbewertungsverfahren nach

Anhang VII

der Richtlinie 93/42/EWG des Rates vom 14. Juni 1993 über Medizinprodukte entspricht.

Diese Konformitätserklärung ist gültig bis 25. Mai 2024.

## Declaration of Conformity

We, the company
G. Pohl-Boskamp GmbH & Co. KG
Kieler Strasse 11
25551 Hohenlockstedt
Germany

declare on our own responsibility that the risk class I medical device (rule 5, dash 2 of annex IX of the directive mentioned below)

**GeloTonsil® Gurgelgel**
Product code: 585

which is subject of this declaration, complies with the requirements of

Annex I

and with the conformity assessment procedure according to

Annex VII

of the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.

This Declaration of Conformity is valid until 25 May 2024.

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Hohenlockstedt, 20 May 2021

Ines Rowedder
Director Medical Device Registration

Dr Maxi Hofrichter
Advisor Medical Device Registration

G. Pohl-Boskamp GmbH & Co. KG
POHL BOSKAMP
Kieler Str. 11 25551 Hohenlockstedt
Pharmaceuticals since 1835 Germany

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## Manufacture's Declaration

in relation to Regulation (EU) 2023/607 amending Regulation (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market.

We, the company G. Pohl-Boskamp GmbH & Co. KG
Kieler Strasse 11
25551 Hohenlockstedt
Germany
Single Registration Number: DE-MF-000010001

declare under our sole responsibility:

- the medical devices listed in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market,

namely by fulfilling the following conditions:

- Formal application to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has been made for the devices and a signed written agreement is in place in accordance with Section 4.3, second subparagraph of Annex VII MDR.
- A Quality Management System (QMS) is in place in accordance with Article 10(9) MDR.
- The devices listed in the attached schedule continue to comply with the MDD.
- There are no significant changes in the design and intended purpose.
- The devices do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Hohenlockstedt, 12 February 2024

I. Rowedder

Ines Rowedder
Director Medical Device Registration

G. Pohl-Boskamp GmbH & Co. KG
POHL BOSKAMP
Pharmaceuticals since 1935
Kieler Str. 11 25551 Hohenlockstedt Germany

Lea Dornseiff

Lea Dornseiff
Advisor Medical Device Registration

**Schedule of Devices**

The above Manufacturer's Declaration is valid for the following devices:

| **Identification of the devices** (device name) | **Original expiry date as indicated on the Declaration of Conformities prior to the extension of the validity** | **Notified Body name and number where the MDR application was lodged/contract signed** | **End date of extended validity / transition period** (acc. to article 120.3b of the MDR) |
|---|---|---|---|
| **Sobrade** | 25 May 2024 | DNV MEDCERT GmbH 0482 | 31 December 2028 |
| **GeloTonsil** | 25 May 2024 | DNV MEDCERT GmbH 0482 | 31 December 2028 |

- End of list -