



## Konformitätserklärung

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

erklären in eigener Verantwortung, dass das Produkt

**Saseem® Mundspray**  
Rezepturcodierung: 660

auf das sich diese Erklärung bezieht, den Anforderungen des Anhang I

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

Klasse IIa

dieser Richtlinie (Anhang IX, Regel 5, 3. Spiegelstrich) einzustufen ist.

Die Benannte Stelle  
*MedCert Zertifizierungs- und  
Prüfungsgesellschaft für die Medizin GmbH  
Pilatuspool 2  
20355 Hamburg  
Deutschland*

mit der Kennnummer 0482 war eingeschaltet zur Durchführung des Konformitätsbewertungsverfahrens nach Anhang V der Richtlinie 93/42/EWG und hat hierüber die Bescheinigungen Nr. 3253DE414200610 (deutsch) und 3253GB414200610 (englisch) gültig bis zum 27. Mai 2024 ausgestellt.

Diese Konformitätserklärung ist gültig bis 27. Mai 2024.

Hohenlockstedt, 20 May 2021

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

*I. Rowedder*

Ines Rowedder  
Director Medical Device Registration

## 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 product

**Saseem® Mundspray**  
Rezepturcodierung: 660

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

of the Council Directive 93/42/EEC of 14<sup>th</sup> of June, 1993 concerning medical devices and has to be categorized according to

Class IIa

of this Directive (Annex IX, rule 5, 3<sup>rd</sup> dash).

The Notified Body  
*MedCert Zertifizierungs- und  
Prüfungsgesellschaft für die Medizin GmbH  
Pilatuspool 2  
20355 Hamburg  
Germany*

with the Identification Number 0482 was involved in the conformity assessment according to Annex V of the Directive 93/42/EEC and has issued the certificates no. 3253DE414200610 (German) and 3253GB414200610 (English) valid until 27 May 2024.

This Declaration of Conformity is valid until 27 May 2024.



*M. Hofrichter*

Dr. Maxi Hofrichter  
Advisor Medical Device Registration



## Manufacturer's Declaration

in relation to 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, in particular with respect to

- the validity of certificates issued under Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) and
- 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 on our own responsibility:

- for the Directive Certificates listed in the attached schedule the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met and
- the listed devices 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:

- Directive Certificates covering the listed devices were issued after 25 May 2017 and were valid on 26 May 2021 and have not been withdrawn afterwards.
- Formal applications to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment have been made for the listed 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 in accordance with Article 10(9) MDR is in place.
- 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 listed in the attached schedule 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, 10 April 2024

*Lea Dornseiff*

Lea Dornseiff  
Advisor Medical Device Registration



*Rieke Gotthard*  
Rieke Gotthard  
Advisor Medical Device Registration

**Schedule of Devices**

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

<b>Identification of the devices</b> (Device name)	<b>Directive Certificate number to which this confirmation is made</b>	<b>Original expiry date as indicated on the Directive Certificate prior to the extension of the validity</b>	<b>Notified Body name and number that issued the Directive Certificate</b>	<b>Notified Body name and number where the MDR application was lodged and a written agreement signed</b>	<b>End date of extended validity / transition period (acc. to article 120.3a of the MDR)</b>
GeloRevoice/ GeloVox	3253DE414200610/ 3253GB414200610	27 May 2024	DNV MEDCERT GmbH 0482	DNV MEDCERT GmbH 0482	31 December 2028
GeloSitin					
Saseem					
NYDA express NYDA Läusespray NYDA plus					
LOYON					
Gepan instill	12770DE439190930/ 12770GB439190930 3253DE410200610/ 3253GB410200610	27 May 2024	DNV MEDCERT GmbH 0482	DNV MEDCERT GmbH 0482	31 December 2027

- End of list -