Wearable Adhesives for Medical Devices: 28-day Study

Authors:

Dr. Ruben Friedland, Head of R&D Advanced Adhesives & Medical
Jan Carr, Product Development Manager
Lohmann GmbH & Co. KG

Lohmann
The Bonding Engineers

Introduction

Securing medical wearable devices with skin tapes, requires reliable adhesive performance in terms of shear strength, aging resistance and wear time. The devices, e.g. continuous glucose monitors (CGMs), electrocardiogram monitors, drug delivery systems, insulin pumps and activity trackers are intended to be worn for days up to several weeks. To increase usability and decrease costs, the demand of increased wear time has grown significantly and by these the meaning of the phrase "extended wear time". In the close past, extended wear time meant 3 up to 7 days, nowadays the commercially available state-of-the-art is at a minimum of 14 days, with the requirements of some major OEMs of medical wearable devices for a wear time of 21 to 28 days.
This study determines the wear time of eight different tape constructions with 3D printed mock wearable devices (Figure 1) on non-compromised skin of healthy volunteers over a time period of 28 days.

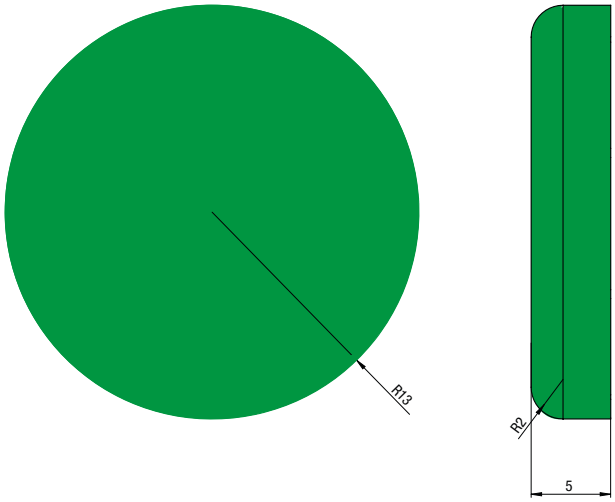


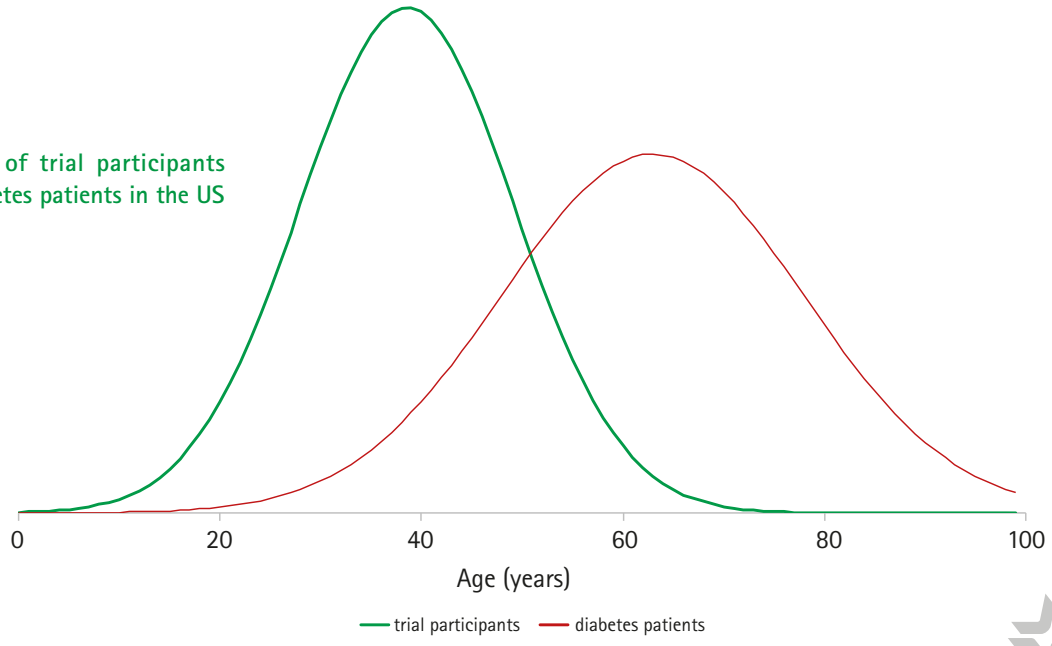
Figure 1:
3D printed mock wearable device

Methods

The in-house wear study was performed in controlled conditions on the upper arms of healthy trial participants. The study was a prospective, randomized study, conducted with non-sterile samples on 39 healthy volunteers (14 females and 25 males) with an average age of 39 years (from 20 years up to 60 years of age; Figure 2). Compared to the typical age distribution for diabetes patients in the US, with an average age of 63 years, the age distribution of the wear study is more critical for adhesive wear time, as younger people have a higher rate of cell renewal than older people. Therefore, loss of adhesion is more likely.

The aim of the study was to evaluate the extended wear performance of 5 newly developed adhesives benchmarked against Duplo**MED® 22791** and two competitive skin adhesives with mock wearable devices for up to 28 days (Table 1, Figure 3). The test adhesives were subjected to a toxicology assessment before the study and certified by an external laboratory for DIN EN ISO 10993-5:2009 and DIN EN ISO 10993-10:2021 compliance for skin and body contact.

Figure 2:
Age distribution of trial participants compared to diabetes patients in the US



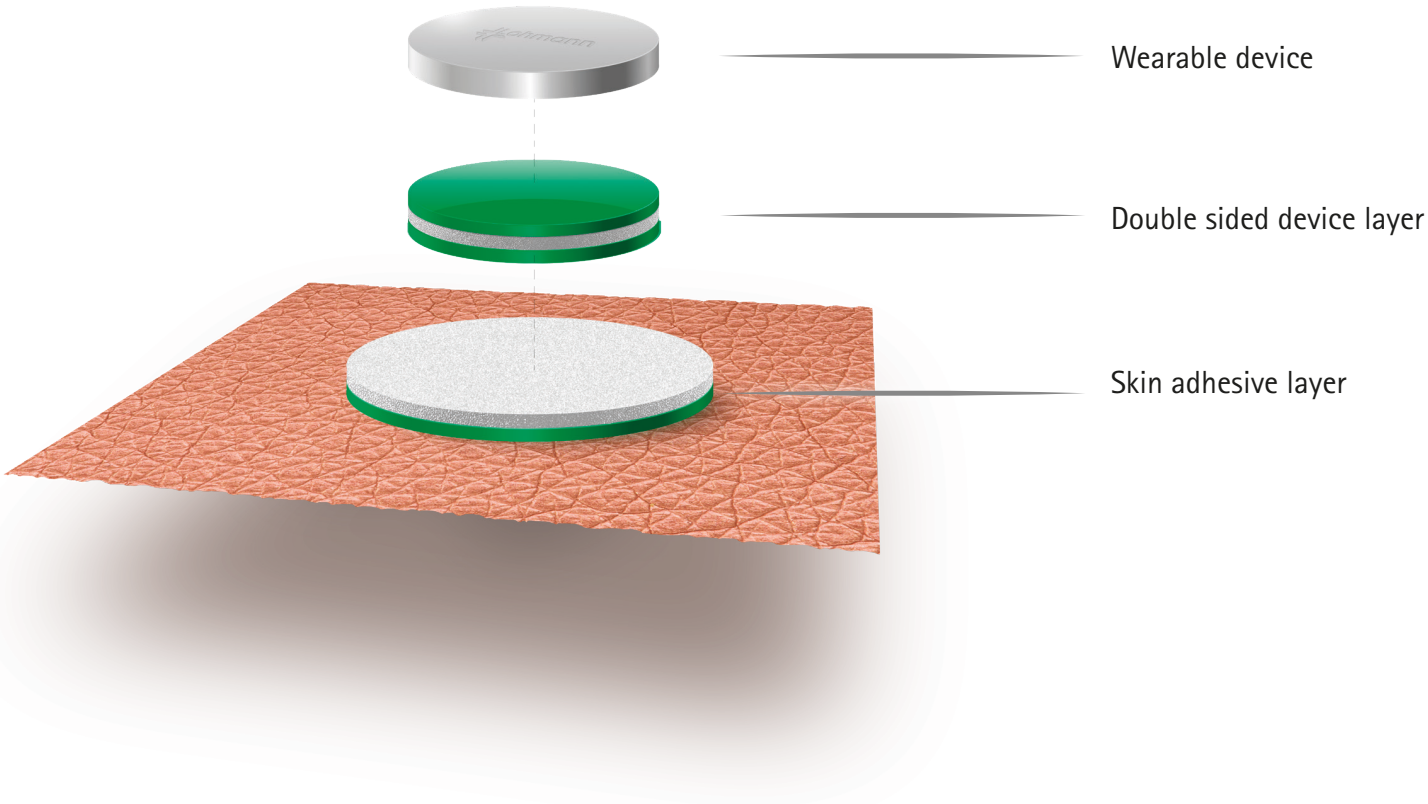
In this whitepaper, for the sake of clarity, out of 8 tested tapes only the results of the internal benchmark, the best-performing new development and two competitors are taken into consideration.

The designations (Adhesive ID) in Table 1 refer to the skin tape, as this was the primary subject of the study.

Table 1:
Skin adhesive constructions

	DuploMED® 22791 (Green)	Test adhesive 1 (Red)	Competitor A (Yellow)	Competitor B (Black)
Adhesive ID	3	2	1	4
Adhesive construction	Polyurethane nonwoven	Polyurethane nonwoven	Polyester nonwoven	Polyurethane nonwoven
	Acrylic adhesive 2	Acrylic adhesive 1	Acrylic adhesive	Acrylic adhesive

Figure 3:
The prototypical device refers to a CGM device in shape and weight



Participants were asked to clip excessive hair, if necessary, and omit from using moisturizers or other skin contacting materials on their arms 24-hours prior to the study. On Day 0 (zero) of the study the skin was assessed by the study directors, before the areas were washed with a mild soap solution, rinsed, patted dry and cleaned with alcohol wipes (70 % isopropanol). All devices were applied to the upper arms (Figure 5) and worn for up to 28 days to evaluate the survival rate. Physical activities, showering or bathing behavior, but also the adherent status of the patches and the wearing comfort were assessed by the participants and recorded daily. These data were logged using an app, with a photo being transmitted at the same time, on which basis the study directors were able to assess the skin condition. All activities including swimming, hot tubs, baths, and sauna were fully allowed during the 28 days. Pain upon removal was noted at the end point of 28 days. The participants were asked to rate their pain on a numeric scale (0-10) with 0 corresponding to "no pain" and 10 corresponding to "worst pain" based on the Wong-Baker FACES® Pain Rating Scale (Figure 4).

Figure 4:
Wong-Baker FACES® Pain Rating Scale

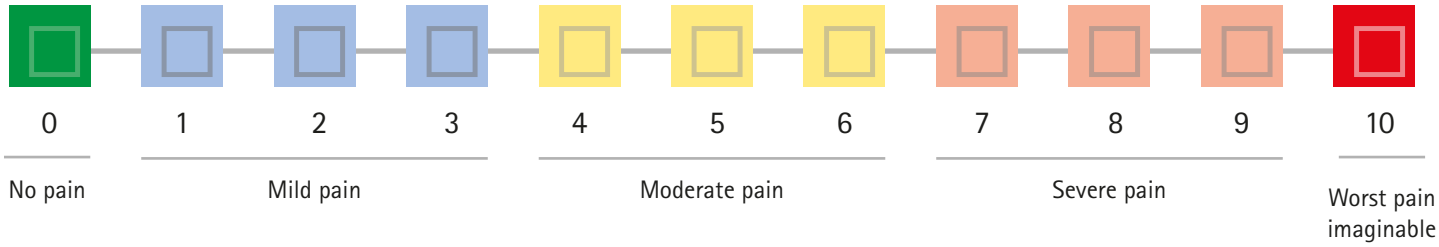
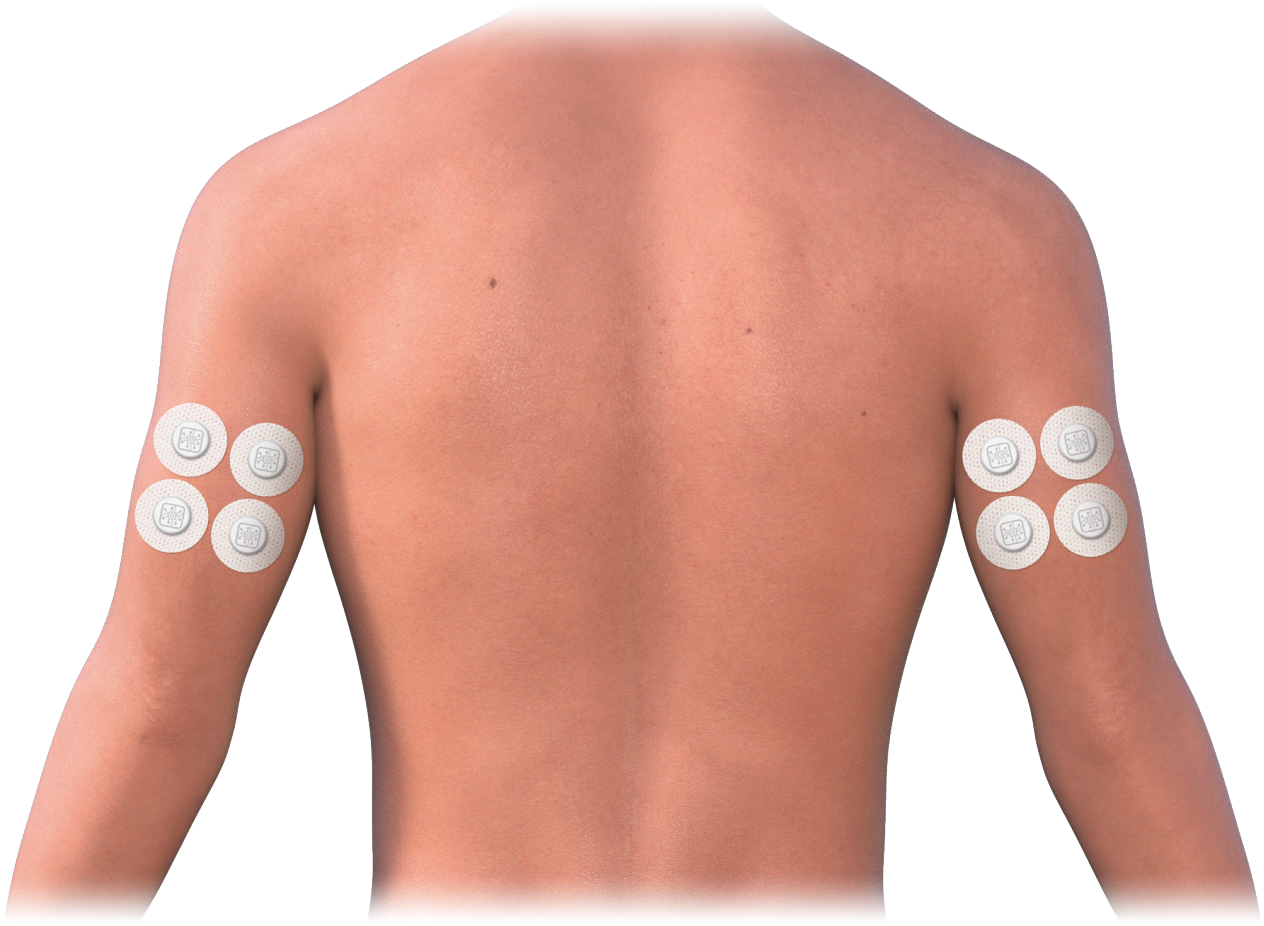


Figure 5:
Illustration of sample placement on the arm



Results

All 39 participants of the wear study wore the devices until they fell off unintentionally or until the completion of 28 days. None of the participants removed their prototypes due to skin irritation or other reasons. Partial detachment, edge lifting, itching, wear comfort were noted by the test participants and assessed by the study directors on a daily basis via photos and information provided. All participants reported minimal to no itching over the 28 days.
Table 3 summarizes the percentage of adhesives still adhered to skin (survival rate) at 7, 14, 21 and 28 days.

Table 2:
Survival rate of each skin adhesive at 7, 14, 21 and 28 days

	DuploMED® 22791 (Green)	Test adhesive 1 (Red)	Competitor A (Yellow)	Competitor B (Black)
Adhesive ID	3	2	1	4
Survival rate at 7 days	92 %	100 %	95 %	95 %
Survival rate at 14 days	74 %	97 %	74 %	87 %
Survival rate at 21 days	67 %	87 %	67 %	72 %
Survival rate at 28 days	49 %	72 %	46 %	62 %

The mean value of the survival rate of all skin adhesives as a function of wear time is shown in Figure 6. A survival rate greater than 85 % correlation to the intended lifetime of the device at these time periods is considered as a very good result given that multiple skin types are highly variable and can be challenging to adhere to.
The graph indicates that at 14, 21 and 28 days, "Test adhesive 1" has a higher survival rate than all other tested products. As a result of the good values, "Test adhesive 1" was standardized as DuploMED® 85300 and is now commercially available. The second-to-best tape tested, competitor B, has a survival rate that is significantly lower. Additionally, the survival curve of benchmark DuploMED® 22791 is similar to competitor A over the 28 day wear time. The lower starting value of DuploMED® 22791 and competitor B at day 0 is due to a test person with a skin type that is difficult to adhere to. These two products lost adhesion within the first 2 hours, whereas competitor A and DuploMED® 85300 (Test adhesive 1) remained adhered.

Figure 6:
Survival curves, illustrating the outstanding performance of the new Lohmann development as a function of wear time

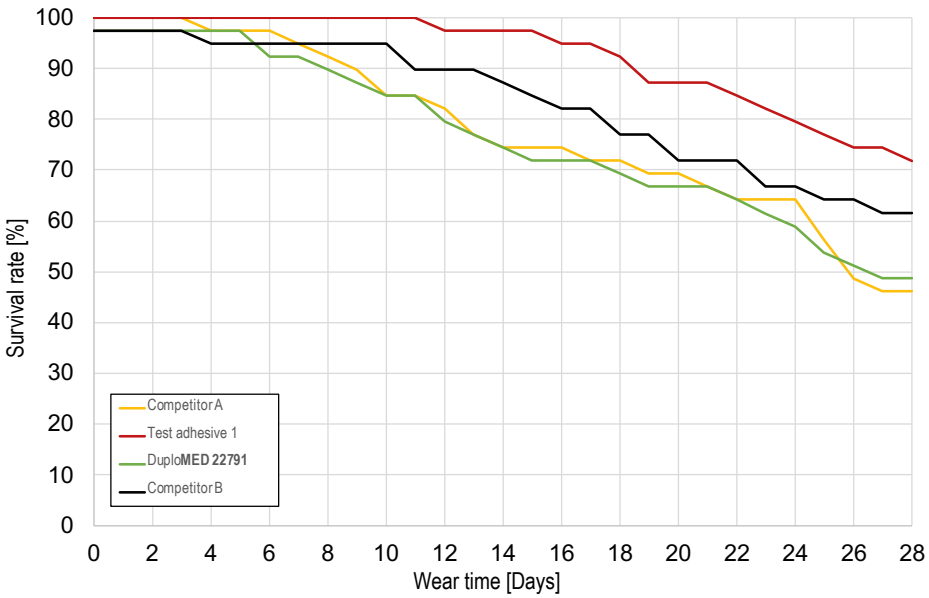
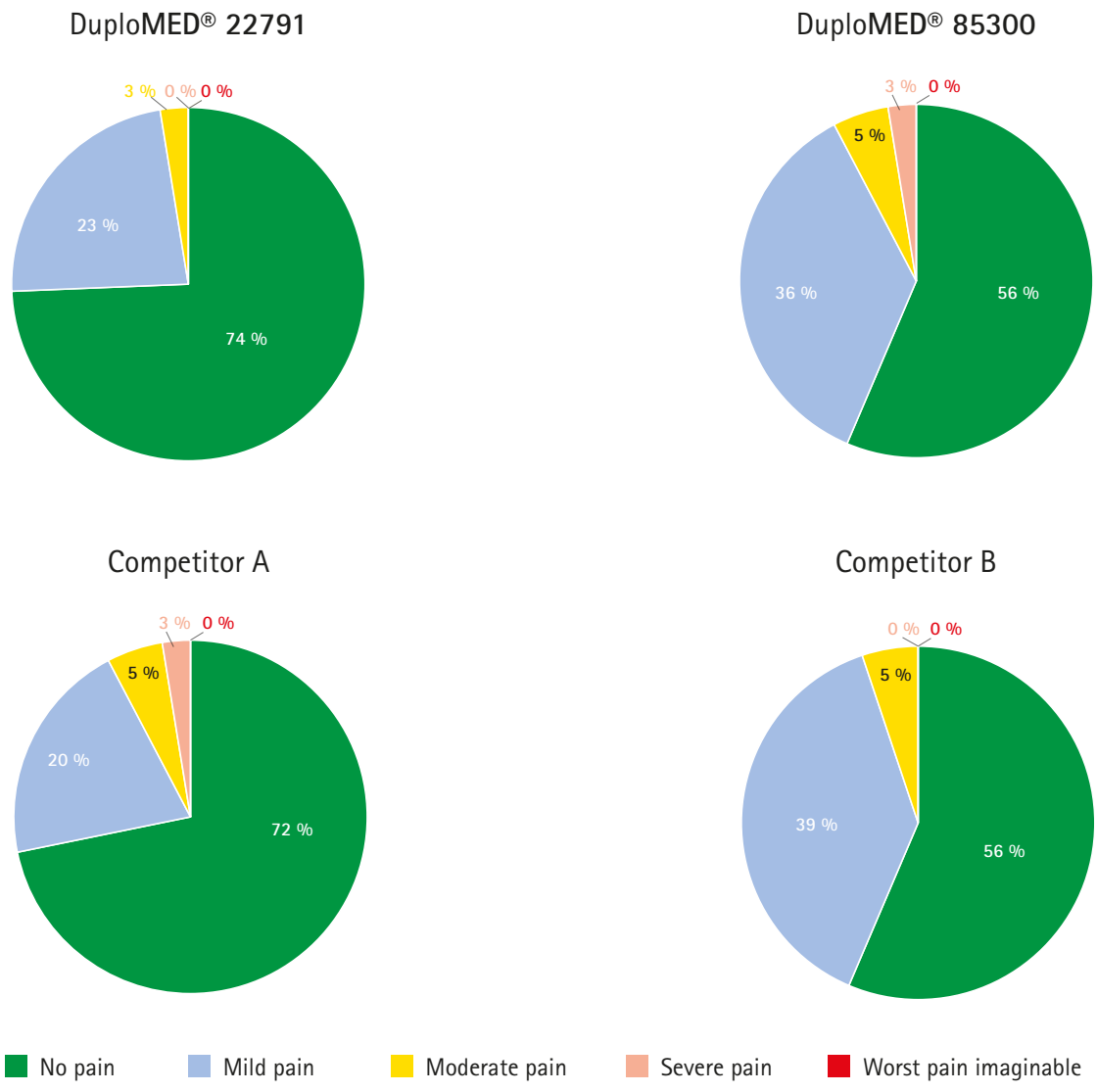


Figure 7 shows the pain level of skin patches when removed after 28 days. The adherence of the adhesive decreases with increasing wear time and, therefore, has a major effect on pain perception. Therefore, survival rate and pain rate correlate: the lower the survival rate, the lower the pain rate, as the adherence is significantly lower at 28 days. It is noteworthy, that DuploMED® 85300, with a significantly higher survival rate of 72 %, has a similar pain perception as competitor B.

Figure 7:
The majority of trial participants experienced no pain during removal after 28 days



Summary

Acknowledging the complexity of various commercial devices and multiple skin types, the desired performance attributes and user requirements are critical in selecting the right adhesive system for wearable medical devices.

The primary goal of this wear study was to evaluate the extended 28-day wear time of different skin adhesive products. A total of eight different skin adhesives (5 investigational, 3 commercially available) were worn with a mock wearable device. The mock wearable device was included in this study to provide a load and simulate the intended use scenario. Physical activities such as swimming, hot tubs, bathing, and sauna, were allowed during the 28 days of the wear study. Wear time was based on adherence of the adhesives and prototype devices to the skin.

For the sake of reducing complexity, in this whitepaper, only the best performing tape, an internal benchmark and two competitor tapes are discussed.

Based on the results of this study, two wearable products are now available, which can be used depending on the application and wear times desired. Duplo**MED® 22791** is a product for wear times up to 14 days, which has good adhesion and results in a low level of pain at 14 days on removal. In addition, Duplo**MED® 85300** was developed for longer wear times of up to 28 days and has very good adhesion even for challenging skin types that are difficult to adhere to.

Be the first to get informed about new whitepapers, products and webinars! Subscribe to our newsletter!

BONDED

Get in touch

With decades of know-how in the medical industry, we happily accompany you throughout your entire process and answer all your questions.

Get in touch with us by simply scanning the qr-code or visit our website.

www.lohmann-tapes.com/wearables

Lohmann
The Bonding Engineers