

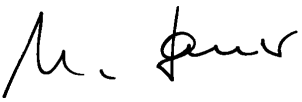


## SAUER-Hautkleber



**Konformitätserklärung / Declaration of Conformity /  
Déclaration de Conformité / Dichiarazione di Conformità**

|                                                                                                               |                                                                                |                                                                                                      |                                                                                                        |
|---------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------|
| Wir,                                                                                                          | We,                                                                            | Nous,                                                                                                | Noi,                                                                                                   |
| <b>Manfred Sauer GmbH,<br/>Neurott 7, 74931 Lobbach, Germany</b>                                              |                                                                                |                                                                                                      |                                                                                                        |
| erklären in alleiniger Verantwortung, dass das <b>Medizinprodukt</b>                                          | declare on our own responsibility that the <b>medical device</b>               | déclarons sous notre propre responsabilité que le <b>dispositif médical</b>                          | dichiariamo sotto propria responsabilità che il <b>dispositivo medico</b>                              |
| <b>SAUER-Hautkleber</b>                                                                                       |                                                                                |                                                                                                      |                                                                                                        |
| <b>SAUER-Hautkleber</b>                                                                                       | <b>SAUER skin adhesive</b>                                                     | <b>Colle-peau SAUER</b>                                                                              | <b>Mastice adesivo per pelle SAUER</b>                                                                 |
| inklusive der Varianten (falls zutreffend, siehe Beiblatt)                                                    | including the variants (if applicable, see enclosed sheet)                     | inclusive des variantes (le cas échéant, consulter la notice jointe)                                 | Incluse le varianti (se applicabili, vedi supplemento)                                                 |
| allen Anforderungen der Medizinprodukte-Richtlinie 93/42/EWG entspricht.                                      | meets all the provisions of the Directive 93/42/EEC                            | remplit toutes les exigences de la directive sur les dispositifs médicaux 93/42/CEE                  | adempie a tutte le esigenze della Direttiva 93/42/CEE                                                  |
| <b>Angewandte harmonisierte Normen:</b>                                                                       | <b>Applied harmonised standards:</b>                                           | <b>Normes harmonisées appliquées :</b>                                                               | <b>Norme armonizzate applicate:</b>                                                                    |
| <b>EN ISO 14971, EN 980, EN 1041, EN 12182, EN ISO 13485, EN ISO 10993-1, EN ISO 10993-5, EN ISO 10993-10</b> |                                                                                |                                                                                                      |                                                                                                        |
| <b>Klassifizierung</b><br>basiert auf den Anforderungen der <b>Regel</b>                                      | <b>Classification</b><br>is based on the requirements of <b>Rule</b>           | <b>Classification</b><br>est fondée sur les exigences de la <b>Règle</b>                             | <b>Classificazione</b><br>basata sui requisiti della <b>regola</b>                                     |
| <b>1</b>                                                                                                      |                                                                                |                                                                                                      |                                                                                                        |
| des <b>Anhang IX</b> der Richtlinie über Medizinprodukte Medizinprodukt der <b>Klasse</b>                     | of <b>annex IX</b> of the Medical Device Directive Medical device <b>Class</b> | de l' <b>annexe IX</b> de la directive sur les dispositifs médicaux Dispositif médical <b>Classe</b> | dell' <b>Allegato IX</b> della direttiva sui dispositivi medici Dispositivo medico della <b>classe</b> |
| <b>I</b>                                                                                                      |                                                                                |                                                                                                      |                                                                                                        |
| Konformitätsbewertungsverfahren gemäß der Richtlinie 93/42/EWG, Anhang                                        | Conformity assessment procedure according to Directive 93/42/EEC, Annex        | Procédure d'évaluation de la conformité en application de la directive 93/42/CEE Annex               | Procedura di valutazione della conformità secondo la direttiva 93/42/CEE, Allegato                     |
| <b>VII</b>                                                                                                    |                                                                                |                                                                                                      |                                                                                                        |
| Benannte Stelle (falls zutreffend)                                                                            | Notified body (if applicable)                                                  | Organisme notifié (le cas échéant)                                                                   | Organo notificato (se il caso)                                                                         |
| <b>—</b>                                                                                                      |                                                                                |                                                                                                      |                                                                                                        |
| Gültig bis                                                                                                    | Valid until                                                                    | Valable jusqu'au                                                                                     | Valida fino al                                                                                         |
| <b>2013-12-01</b>                                                                                             |                                                                                |                                                                                                      |                                                                                                        |

|                                |                               |                                                                                                                                   |                               |
|--------------------------------|-------------------------------|-----------------------------------------------------------------------------------------------------------------------------------|-------------------------------|
| Ort, Datum /<br>Name, Funktion | Place, Date<br>Name, Function | Lieu, Date<br>Nom, Fonction                                                                                                       | Luogo, Data<br>Nome, Funzione |
| Lobbach, 01.12.2008            |                               | <br><b>Manfred Sauer</b><br>Managing Director |                               |



## SAUER-Hautkleber



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| Varianten / Variants / Variantes / Varianti        | Best.-Nr. / REF  |
|----------------------------------------------------|------------------|
| <b>D SAUER-Hautkleber – 12 % Harz</b>              | 50.22            |
| E SAUER skin adhesive – 12 % resin                 |                  |
| F Colle-peau SAUER – 12 % de résine                |                  |
| I Mastice adesivo per pelle SAUER – 12 % di resina |                  |
| <b>D SAUER-Hautkleber – 2 % Harz</b>               | 50.20            |
| E SAUER skin adhesive – 2 % resin                  |                  |
| F Colle-peau SAUER – 2 % de résine                 |                  |
| I Mastice adesivo per pelle SAUER – 2 % di resina  |                  |
| <b>D SAUER-Hautkleber – 50 %</b>                   | 50.05            |
| E SAUER skin adhesive – 50 %                       |                  |
| F Colle-peau SAUER – 50 %                          |                  |
| I Mastice adesivo per pelle SAUER – 50 %           |                  |
| <b>D SAUER-Hautkleber – Lanolinfrei</b>            | 50.03            |
| E SAUER skin adhesive – Without lanolin            |                  |
| F Colle-peau SAUER – Sans lanoline                 |                  |
| I Mastice adesivo per pelle SAUER – Senza lanolina |                  |
| <b>D SAUER-Hautkleber – Original</b>               | 50.01            |
| E SAUER skin adhesive – Original                   |                  |
| F Colle-peau SAUER – Normale                       |                  |
| I Mastice adesivo per pelle SAUER – Originali      |                  |
| <b>D SAUER-Hautkleber – Pur</b>                    | 50.00            |
| E SAUER skin adhesive – Pure                       |                  |
| F Colle-peau SAUER – Pure                          |                  |
| I Mastice adesivo per pelle SAUER – Pura           |                  |
| <b>D SAUER-Hautkleber – Syn</b>                    | 50.36<br>50.36-2 |
| E SAUER skin adhesive – Synthetic                  |                  |
| F Colle-peau SAUER – Syn                           |                  |
| I Mastice adesivo per pelle SAUER – Syn            |                  |
| <b>D SAUER-Hautkleber – Weiß</b>                   | 50.31            |
| E SAUER skin adhesive – White                      |                  |
| F Colle-peau SAUER – Blanche                       |                  |
| I Mastice adesivo per pelle – Bianco               |                  |