

Corrective actions concerning the reclamation of Brilliant mouth-mirrors No. 4 on 8th March 2012

Deviation: Mirror part has fallen out of its frame

Immediate actions:

Inspection of mouth mirrors in our stock: all were ok. The incident was reported to BfArM. Return call performed by Purchasing Department without delay.

Root cause analysis:

Until December of 2011 the mirror part was fixed to the socket by an adhesive. Batch 4/31 had in some cases not enough adhesive, so that mirrors fell out. In the most reported cases the mirror already fell out when opening the protective cover or when removing the protective foil covering the mirror.

Corrective actions:

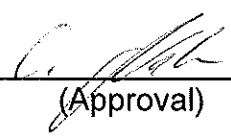
Production process of the mouth mirrors has been changed, so that no adhesive was used any more in order to fix the mirror in place. The mirrors now are fixed in place by mechanic means. This measure was already performed in December 2011. Therefore no new evaluation of the risks is necessary and no further actions concerning that have to be performed. The only measure taken by Hager&Werken was to start an immediate return call of batch 4/31

Preventive Actions:

None

Examination of effectiveness:

The effectiveness can already be evaluated by examining the new batch. Mirror is fixed in place and cannot fall out.



(Approval)



(Date)