

# Swiss recommendations on driving ability in patients with diabetes mellitus

Endorsed by the Traffic Medicine Section of the Swiss Society of Legal Medicine (SSLM) and the Executive Board of Swiss Society of Endocrinology and Diabetology (SSED)

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## Summary

Most people with diabetes mellitus operate motor vehicles safely without creating any meaningful risk on the road for themselves or others. A diagnosis of diabetes is, in itself, inadequate for determining a person's driving capability or safety. Diabetes-related traffic accidents are rare for most drivers with diabetes mellitus and occur less frequently than for many other diseases that can impair driving performance and that are tolerated by society. The incidence of hypoglycaemia, which impairs the ability to drive, severe retinopathy (including macular oedema) or cataract formation affecting visual acuity required to drive a motor vehicle, and peripheral neuropathy, which can severely impair sensation in the feet, is not so common as to justify restricting driving privileges for all drivers with diabetes mellitus.

In recent years, several pharmacological and technological innovations have revolutionised diabetes care. Continuous glucose monitoring system (CGMS) technology has only recently become increasingly integrated into diabetes therapy. Today, except for insulin, none of the treatments recommended for type 2 diabetes mellitus causes hypoglycaemia, and the risk of hypoglycaemia with ultra-long-acting insulins is lower. As a result, recommendations for driving motor vehicles have had to be adjusted. Since hypoglycaemia is the greatest risk factor for impaired driving ability, the latest technology (CGMS coupled with hybrid closed-loop insulin pumps) can reduce the number of hypoglycaemic events and blood glucose fluctuations. In addition, HbA1c and time in target range can be improved. Patients with type 1 diabetes mellitus are now, in exceptional cases, allowed to be licensed in higher vehicle categories. With the analysis of CGMS data, an objective assessment of the frequency of hypoglycaemia is now possible; this was previously only partially possible with blood glucose logs. Patients who are treated with insulin should use a CGMS. This also applies to gestational diabetes and diabetes during pregnancy. Since these sys-

tems warn of impending hypoglycaemia, they will also improve road safety, and the safety margin for blood glucose, previously set at 5 mmol/l, can be lowered to 4 mmol/l. For CGMS users, blood glucose measurements every 2 hours while driving are no longer necessary.

## Introduction

The prevalence of diabetes mellitus in Switzerland is 6.3% [1] and most of these people operate motor vehicles safely without creating any meaningful risk on the road for themselves or others. A diagnosis of diabetes is, in itself, inadequate for determining a person's driving capability or safety. In addition, diabetes mellitus is only recorded on the driver's licence if the diagnosis already existed at the time the licence was issued (this applies in particular to young patients with type 1 diabetes mellitus or monogenetic forms of diabetes). Otherwise, the diagnosis of diabetes is only recorded on the driver's licence in the event of a motor vehicle accident; for drivers aged over 75, all of whom undergo assessment of fitness to drive; for people who drive a motor vehicle professionally (cab, truck, bus driver). The majority of people with diabetes mellitus are, therefore, never registered by road traffic authorities. The treating physician has the right, but no obligation, to report patients with diabetes mellitus with reduced fitness to drive to the relevant authorities.

Diabetes-related traffic accidents are rare for most drivers with diabetes mellitus and occur less frequently than for many other diseases that can impair driving performance and are tolerated by society. The incidence of hypoglycaemia, which impairs the ability to drive, severe retinopathy (including macular oedema) or cataract formation affecting visual acuity required to drive a motor vehicle, and peripheral neuropathy, which can severely impair sensation in the feet, is not so common as to justify restricting driving privileges for all drivers with diabetes mellitus.

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## Accident risk in patients with diabetes mellitus

Although the above-mentioned complications of diabetes mellitus can increase the risk of motor vehicle accidents, incapacitation from hypoglycaemia poses the highest risk of accidents. The risk exists in people who are treated with insulin, sulfonylureas or glinides. A study in drivers treated with insulin concluded that 13% had developed hypoglycaemia while driving in the previous year [1]. The analysis of various studies has shown that there is an increased risk of traffic accidents, but it is very modest [2]. A meta-analysis showed that the risk of traffic accidents among drivers with diabetes mellitus was not higher than among drivers without diabetes mellitus. Elderly people [3] and those on insulin therapy showed a trend towards an increased risk, but statistical significance was clearly missed [4]. Some published studies suggest that drivers with type 1 diabetes have a slightly higher risk of traffic accidents compared to drivers with type 2 diabetes (insulin and/or sulfonylureas). A driver with type 2 diabetes has the same risk as a driver without diabetes [5], but this has not been confirmed by other studies [6]. Case-control studies have shown that drivers with diabetes mellitus have only a slightly increased and, therefore, acceptable risk of motor vehicle accidents compared to drivers without diabetes, but many studies have significant limitations or are of poor quality. In particular, severe hypoglycaemia is very common in a very small percentage of patients (especially those with longstanding diabetes and under insulin therapy) and thus increases the risk of accidents in the entire group. Older studies may no longer be up-to-date due to changes in road conditions, motor vehicles and, above all, advances in the treatment of diabetes mellitus: more and more continuous blood glucose monitoring [7] in type 1 and type 2 diabetes, hybrid closed-loop insulin pumps in type 1 diabetes mellitus, no more use of sulfonylureas and much better ultra-long-acting insulins with a lower risk of hypoglycaemia. However, one question remains: How frequently does blood glucose need to be measured? An observational study with a continuous glucose monitoring system (CGMS) has shown that with a blood or sensor glucose level  $\geq 5$  mmol/l at the start of driving, a blood glucose level  $< 3.9$  mmol/l is reached within two hours in 13.8% of patients with type 1 and in 4.4% with type 2 diabetes mellitus treated with insulin. After 4 hours it is even 22% and 8.4%, respectively [7].

In summary, most drivers with diabetes safely operate motor vehicles without creating any meaningful risk of injury to themselves or others. Diabetes mellitus alone is, therefore, not synonymous with impaired fitness to drive, and the increasing adoption of diabetes technologies and improved medications are likely to further reduce or prevent the frequency of hypoglycaemia [8].

## Legal basis of guidelines on fitness to drive in patients with diabetes mellitus compared to other diseases

For other diseases, specific requirements have been defined by traffic medicine and the relevant professional associations, and such an approach has also been chosen for diabetes mellitus.

## Legal basis

According to Art. 14 of the Road Traffic Act (SVG), anyone who fulfills the following criteria is allowed to drive a motor vehicle: is above the minimum age; has the necessary physical and mental capacity to drive motor vehicles safely; does not have an addiction; and has the capacity, judged by their previous behaviour, to follow the regulations as a motor vehicle driver. Fitness to drive describes the general, non-temporal and non-event-related suitability to drive a vehicle safely. On the other hand, *ability to drive* describes the event-related and time-limited ability to drive a vehicle safely, based on current physical and mental capacity.

Furthermore, Art. 7 Para. 1 of the Traffic Licensing Ordinance (VZV) states that anyone wishing to obtain a learner's permit, driver's licence or a permit for professional passenger transport has to meet the *minimum medical requirements* set out in VZV Annex 1.

In the first medical group (categories A, B, A1, B1, F, G, M and subcategory D1 if acquired under old law [entry 106] and limited to 3.5 tons), the minimum requirement mandates that in the presence of diabetes mellitus there must be stable blood glucose control without hypoglycaemia or hyperglycaemia affecting driving ability (VZV Annex 1).

In the second medical group (categories C, D, C1, D1 if not acquired under old law, the permit for professional passenger transport, traffic experts), the VZV mandates that drivers are excluded from category D or subcategory D1 if hypoglycaemia may occur as a side effect of treatment or in which hyperglycaemia may impair the ability to drive. A permit to drive for category C or subcategory C1, for professional passenger transport and for traffic experts, may be given under favourable circumstances (VZV Annex 1).

The local authority may, as an *exception*, deviate from the minimum medical requirements according to VZV Art. 7 Para. 3 if the applicant meets the driving suitability requirements under SVG Art. 14 Para. 2 and a doctor with level 4 recognition (Traffic Medicine Specialist of the Swiss Society of Legal Medicine [SSLM]) confirms this. This is always an individual case assessment by the authorities.

According to the *reporting right* under SVG Art. 15d Para. 3, doctors may report individuals with a reduced fitness to drive to the local road traffic authority without violating medical confidentiality.

In summary, there is a legal basis for fitness to drive, minimum medical requirements for driver's licence categories and the possibility of obtaining an exemption-based permit when deviating from the minimum medical requirements. Hypoglycaemia is the most important factor that leads to a restriction of driving ability. Exceptions can be made for drivers with diabetes who can avoid hypoglycaemia using the most advanced technological methods. Regardless of the reporting right, a doctor is obliged to inform their patients about driving suitability. The medical duty of disclosure and pointing out measures for reducing hypoglycaemia is part of the safety counselling.

## Hypoglycaemia and driving ability

The most important factor in diabetes mellitus that leads to a restriction of driving ability is hypoglycaemia. Hypoglycaemia only occurs when patients are treated with insulin, sulfonylureas or glinides. The risk of hypoglycaemia is higher for sulfonylureas with a longer half-life or with active metabolites. Short-acting glinides and glimepiride, which has no active metabolites and a relatively short half-life, have the lowest rate of hypoglycaemia. The same applies to the ultra-long-acting insulins, degludec (Tresiba®) and glargine 300 (Toujeo®) with more stable pharmacodynamic profiles [8].

A noticeable change in driving behaviour was seen in the latest trials examining the influence of hypoglycaemia (both in simulators and real cars). The lower the glucose concentration (venous blood sugar <2.5 mmol/l and lasting more than 15 minutes), the more pronounced the reduction of driving ability. Hypoglycaemia in the range of 3.0 to 3.5 mmol/l reduced driving ability to a lesser degree. Typical changes include less proactive driving behaviour, reduced fine motor skills and more abrupt reactions. It can be indirectly concluded that blood sugar levels above this range, and especially above 3.9 mmol/l with stable values, are unlikely to have a significant impact on driving behaviour [9, 10]. This aligns with earlier research findings and corresponding international guidelines.

In England and Canada, a blood sugar level of 4.0 mmol/l before driving is considered safe for patients treated with insulin. For blood sugar <4.0 mmol/l, it is recommended to immediately stop the vehicle, remove the ignition key, switch from the driver's seat to the passenger seat, correct the low blood sugar with rapidly acting carbohydrates and wait 45 minutes before resuming the drive [11]. It should also be noted that when hypoglycaemia is corrected, there may be a lag before a CGMS displays normal blood sugar values (in case of doubt, a capillary blood glucose measurement is recommended).

## Factors in diabetes mellitus that impair fitness to drive

Some micro- and macrovascular complications can lead to impaired driving ability over a prolonged period. The best predictive factor for development of these complications is glycaemic exposure, expressed as HbA1c-years (the annual average of HbA1c values is accumulated and every HbA1c value >6.0% is counted. A similar approach is used for smoking with "pack-years"). When 50–70 HbA1c-years are reached, practically all microvascular complications are present [12, 13]. Untreated arterial hypertension, hypercholesterolaemia, smoking and visceral obesity exacerbate these effects. Severe impairment of visual acuity and the visual field due to proliferative retinopathy and/or macular oedema, or severe peripheral neuropathy of the lower extremities with loss of sensation, results in inability to properly perceive and operate the accelerator, brake or clutch pedals. Severe chronic kidney disease (eGFR <30 ml/min) increases the risk of hypoglycaemia when taking a sulfonylurea or insulin.

## Pregnancy and diabetes (gestational diabetes and pre-existing diabetes)

Gestational diabetes is now screened for in all pregnant women between the 24th and 28th week of pregnancy using a 75 g oral glucose tolerance test [14, 15]. If the fasting glucose is  $\geq 5.1$  mmol/l or the 1-hour value is  $\geq 10.0$  mmol/l or the 2-hour value is  $\geq 8.5$  mmol/l, gestational diabetes is diagnosed. It is important to note that the blood glucose values must be measured venously and determined in a central laboratory. HbA1c is not suitable for the diagnosis of gestational diabetes. 15–17% of all pregnant women have gestational diabetes or pre-existing diabetes mellitus [16].

If, during the first prenatal visit, the HbA1c value is  $\geq 6.5\%$ , fasting glucose is  $\geq 7.0$  mmol/l or the 2-hour value is  $\geq 11.1$  mmol/l, pre-existing diabetes mellitus is diagnosed. Gestational diabetes can only be diagnosed before the 24th week of pregnancy with a fasting blood glucose  $\geq 5.1$  mmol/l [15].

During the first 16 weeks of pregnancy, insulin sensitivity is increased and potentially more hypoglycaemia occurs with pre-existing type 1 or insulin-dependent diabetes [17], if the daily insulin dose is not reduced. From the 20th week of pregnancy, insulin sensitivity decreases and the total insulin requirement increases accordingly.

From the 20<sup>th</sup> week of pregnancy, the foetal pancreas begins to react to maternal blood sugar spikes [18–20]. The consequence of maternal hyperglycaemia is hyperinsulinaemia (in mother and child) and macrosomia (in the child). For this reason, the blood glucose target values in Switzerland from the 20th week of pregnancy have been set at <5.3 mmol/l while fasting and <8.0 mmol/l at 1 hour postprandially (internationally 7.8 mmol/l or 140 mg/dl) [12]. As approximately 25% of women with gestational diabetes need to be treated with insulin to achieve these target levels, driving was difficult to manage with the 2017 recommendations (blood glucose should never be <5.0 mmol/l before driving). As pregnant women need to measure blood glucose before every meal and 1 hour after eating and before sleeping, continuous glucose monitoring is now recommended in this situation, along with the use of an ultra-long-acting insulin and, if needed, a short-acting insulin. For women with pre-existing type 1 diabetes mellitus, therapy with an hybrid closed-loop insulin pump and continuous blood glucose monitoring is recommended. This increases the time within the pregnancy target range, 3.5–7.8 mmol/l, and reduces the number of hypoglycaemic episodes <3.5 mmol/l during all trimesters and, thus, also the rate of macrosomia of the child. The lower limit for driving ability, 4.0 mmol/l, is the same as outside of pregnancy.

## Contribution of continuous glucose monitoring and hybrid closed-loop insulin pumps as well as ultra-long-acting basal insulins to road safety

The information density of interstitial continuous glucose monitoring is several times higher than that of capillary self-monitoring of blood glucose values. With continuous glucose monitoring, interstitial glucose concentration is determined every five minutes and a 30-minute prediction

is made. Today, all continuous glucose monitoring systems issue a warning if the glucose is predicted to fall below a certain value, which can be set individually. As already mentioned, 2–4 hours after a glucose measurement  $\geq 5.0$  mmol/l before driving, the blood glucose drops to a value  $< 3.9$  mmol/l in 13.8% of patients with type 1 and in 4.4% of patients with type 2 diabetes mellitus treated with insulin. After 4 hours it is even 22% and 8.4%, respectively [7]. This means that with the help of continuous glucose monitoring, the driver can be warned of hypoglycaemia and can correct the blood sugar with carbohydrates before hypoglycaemia occurs. It is possible, therefore, to set the minimum blood glucose levels before driving lower for a continuous glucose monitoring user than for those using capillary self-monitoring of blood glucose alone. The latest hybrid closed-loop insulin pumps also help to prevent hypoglycaemia. In the earliest models, when the hypoglycaemia value (usually 3.9 mmol/l) was reached, the basal insulin application of the pump was stopped. A further development step led to the predictive switch-off of the insulin pump before the occurrence of hypoglycaemia; today these pumps can automatically correct excessively high blood glucose levels and insulin delivery is automatically interrupted when the blood glucose level drops. The only step still missing to achieve a fully automated pump is automatic insulin delivery before a meal without manual input. Today, the patient still has to inform the pump of how much carbohydrate he/she is eating and the necessary amount of insulin is calculated and delivered based on the current blood glucose value (possibly corrective insulin is added) and the stored carbohydrate factor [21]. In the past, only the HbA1c value and the number of severe hypoglycaemia episodes (level 3; external help required or unconsciousness) were used to assess blood glucose control. With the latest technologies, there are many factors that need to be considered (recommended values in brackets): HbA1c value ( $< 7.0\%$ ), hypoglycaemia  $< 3.9$  or level 1 ( $< 4\%$ ) and hypoglycaemia  $< 3.0$  mmol/l or level 2 ( $< 1\%$ ), the coefficient of variation ( $< 36\%$ ) and the time spent in the target range of 3.9–10 mmol/l ( $> 70\%$ ). It is even more efficient to assign a score of 1 (worst) to 4 (best) for each of these four factors and then sum the scores to obtain a single score [22] (table 1).

The most modern continuous glucose monitoring systems coupled with insulin pumps significantly reduce the number of hypoglycaemic episodes and the coefficient of variation and, if the HbA1c is too high, also the HbA1c. This is the reason why certain restrictions on higher vehicle categories can now be removed as exceptions when using these technologies. As an example of such an exception: a cab or truck driver with type 2 diabetes mellitus treated with metformin, a GLP-1 receptor agonist and an SGLT-2 inhibitor

with an HbA1c of 9.0%; he/she needs a basal insulin with the lowest risk of hypoglycaemia (recommended: degludec or glargine 300) and must be willing to wear a continuous glucose monitoring device. In this case, the diabetologist and the department of traffic medicine still have to decide whether to approve this category, as a high HbA1c increases the risk of long-term consequences and road traffic incidents due to the higher risk of cardiovascular events. The same applies to tram, bus and train drivers.

The new Swiss Society for Endocrinology and Diabetes (SSED) recommendations for the treatment of type 2 diabetes mellitus changed as well. The use of sulfonylureas and glinides is no longer recommended. The recommended antidiabetic agents (metformin, SGLT-2 inhibitors, GLP-1 or GLP-1/GIP receptor agonists) given alone or in combination do not cause hypoglycaemia. If insulin has to be used, the ultra-long-acting insulins degludec and glargine 300 are now recommended as they have a significantly lower hypoglycaemic frequency than glargine 100 or insulin detemir; NPH insulin, which carries the highest risk of hypoglycaemia among the long-acting insulins, is no longer recommended. It has also been shown that with the co-formulated insulin Ryzodeg® (30% NovoRapid® and 70% Tresiba®), which is given once or twice daily with the main meals, the same HbA1c can be achieved as with a basal-bolus regimen but with a much lower rate of hypoglycaemia [8].

Basic guidelines for all driver’s licence holders with diabetes mellitus

If diabetes mellitus is present, there must be stable blood sugar control without hypo- or hyperglycaemia relevant to driving. There must be no other metabolic disorders with a significant impact on the ability to drive a motor vehicle safely. In particular, there must be no traffic-relevant secondary complications, which are specified in detail in the first and second medical group below, and no hyperglycaemia.

In addition, the individual risk of hypoglycaemia must be determined for all motor vehicle drivers depending on the type of treatment with particular emphasis on hypoglycaemia unawareness (figure 1 and table 2). This results in different recommendations for action depending on the driver’s licence category, which are listed in the following sections. Special consideration must be given to whether a continuous glucose monitoring system is worn.

For the treating physician, it is crucial to ask about severe hypoglycaemia, since a very high percentage of patients do not mention hypoglycaemia spontaneously. The Clarke score (in the appendix) can also be used to assess hypo-

**Table 1:** Evaluation of continuous glucose monitoring system (CGMS) blood glucose values [22]. Very good glycaemic control: 14–16 points; good glycaemic control: 11–13 points; sufficient glycaemic control: 9–10 points; insufficient glycaemic control:  $< 9$  points.

HbA1c (%)	Coefficient of variation* (%)	Hypoglycaemia $< 3.0$ mmol/l (%)	Time in range 3.9–10 mmol/l (%)	Points
$< 6.5\%$	$\leq 25\%$	$< 1\%$	$\geq 80\%$	4
6.5–6.9%	26–35%	1–4%	70–79%	3
7.0–8.0%	36–49%	5–10%	51–69%	2
$> 8.0\%$	$\geq 50\%$	$> 10\%$	$\leq 50\%$	1

\* Coefficient of variation = (standard deviation  $\times$  100) / glucose

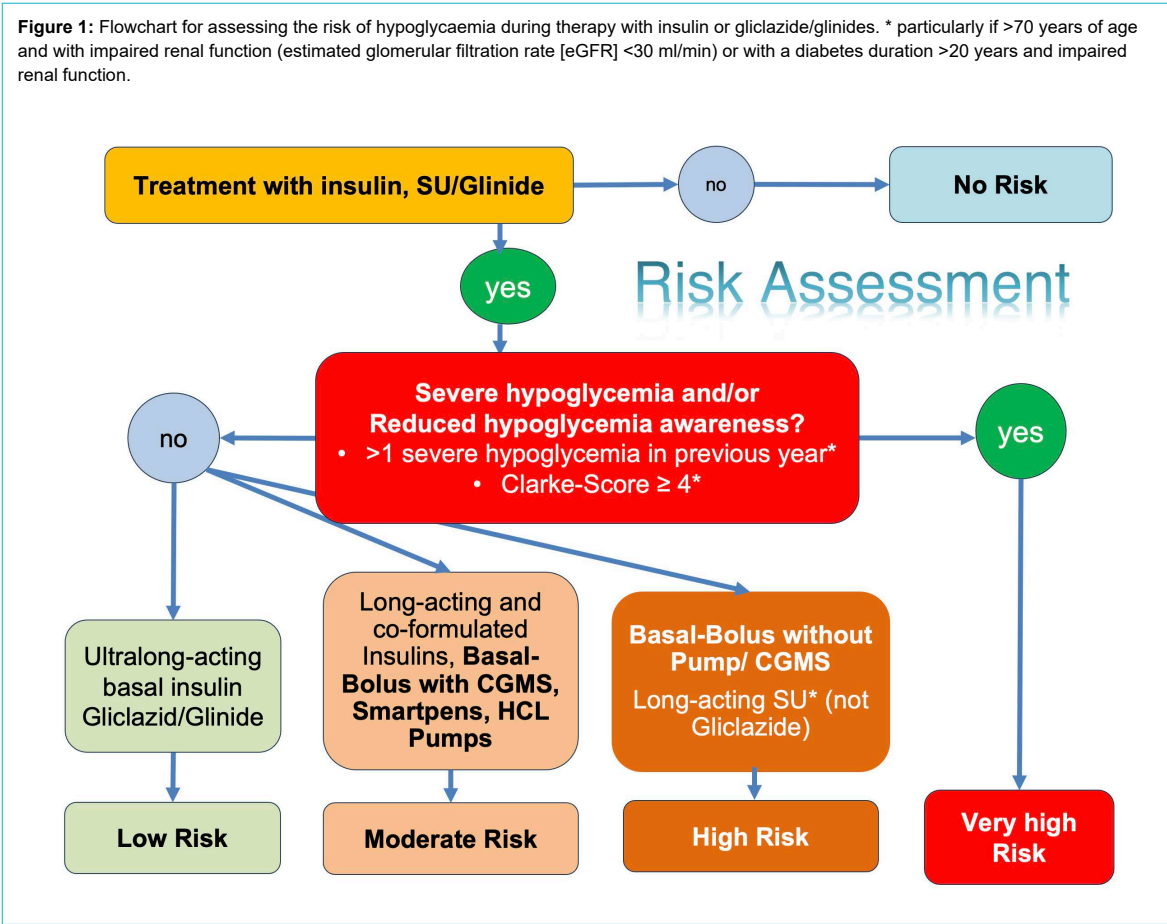


glycaemia awareness. It is the joint responsibility of the treating physician and the patient to avoid severe hypoglycaemia, as this can also lead to serious consequences apart from those affecting driving: higher risk of dementia, more cardiovascular events (including sudden cardiac death), increased risk of thrombosis and more systemic inflammatory reactions [23].

**Guidelines for driver’s licence holders of the first medical group (A, B, A1, B1, F, G, M and C1 for private use)**

The following conditions must be met for initial registration or continued registration as a motor vehicle driver in the first medical group:

- No traffic-relevant diabetes complications (diabetic eye disease impairing vision, nephropathy, neuropathy, no traffic-relevant macrovascular complications)



**Table 2:**  
Overview of risk categories for motor vehicle drivers with diabetes mellitus.

Category	Therapy
No risk	Metformin, GLP-1 receptor agonists, GLP-1/GIP-receptor agonists, DPP-4 inhibitors, SGLT-2 inhibitors or their combination
	and No therapy with insulin, sulfonylureas or glinides
Low risk	Ultralong-acting basal insulins (degludec/glargine 300)
	or Gliclazide or glinides
Intermediate risk	Long-acting insulins (glargine U100, detemir)
	Co-formulated insulin Ryzodeg® 1–2× daily
	or Basal-bolus insulin therapy (incl. smart pens) with continuous glucose monitoring systems (CGMS)
	or Hybrid closed-loop insulin pump systems (HCL)
High risk	Basal-bolus insulin therapy without CGMS
	or Non-hybrid closed-loop insulin pump systems
	or Long-acting sulfonylureas (not gliclazide/glinides)
	≥1 severe hypoglycaemia/year and/or hypoglycaemia unawareness (Clarke Score 4 or higher)

- No traffic-relevant restrictions in the cardiovascular system
- *No significant long-term hyperglycaemia* (no approval or further approval with HbA1c >10%)

### Behaviour before and during driving

In case of treatment with low risk of hypoglycaemia (i.e. ultra-long-acting basal insulin, gliclazide or glinides), blood glucose measurements before driving and during longer trips are not required. However, a blood glucose meter and carbohydrates as hypoglycaemia prophylaxis have to be in the vehicle.

In case of treatment with intermediate risk of hypoglycaemia, we differentiate between the following situations:

- In the case of treatment with long-acting insulins (glargine U100 / detemir), co-formulated insulin (70% degludec and 30% insulin aspart [Ryzodeg®]) or if no continuous glucose monitoring system (CGMS) is used, blood glucose has to be measured before driving and regularly during longer trips (at least every 2 hours) [7]. If the blood sugar is <4.0 mmol/l, it must be corrected by taking carbohydrates before starting or continuing driving. A 45-minute break must be taken. If the blood sugar is 4–5 mmol/l, 10–20 g of carbohydrates have to be consumed.
- In the case of a basal-bolus insulin regimen with a continuous glucose monitoring system (CGMS) or hybrid closed-loop insulin pump system, blood glucose measurements before or during the journey are not necessary, as these systems have an alarm function. If the CGMS shows a downward trend in blood glucose with a risk of hypoglycaemia, this must be corrected early by taking carbohydrates. If the blood glucose is <4.0 mmol/l, carbohydrates must be immediately consumed. Afterwards, a waiting period of at least 45 minutes is required before driving can be resumed (in case of doubt, a capillary blood glucose measurement is recommended).

In case of treatments with high risk of hypoglycaemia (basal-bolus insulin therapy without CGMS, non-hybrid closed-loop insulin pump systems, long-acting sulfonylureas), the blood glucose must be measured before driving and regularly (at least every 2 hours) [7] during longer car trips. If the blood glucose is <5.0 mmol/l, it must be corrected by taking carbohydrates before starting or continuing the journey. Furthermore, for the initial or continued approval as a motor vehicle driver in the first medical group, in addition to the conditions mentioned in the chapter

“Hypoglycaemia and driving ability” (no traffic-relevant late complications, HbA1c <10%), the following conditions must be met:

- *Stable blood glucose control* over the past year without severe hypoglycaemia (Grade III) and without hypoglycaemia unawareness.
- *Stable ability to reliably avoid hypoglycaemia* while driving (i.e. the ability to measure blood glucose before driving and regularly on longer journeys).
- *Adherence to behavioural guidelines*, particularly: The blood glucose must be ≥5.0 mmol/l before driving and

during longer trips (if no CGMS is used) or ≥4.0 mmol/l (if a CGMS is used). If the blood glucose is <5.0 mmol/l (without CGMS) or <4.0 mmol/l (with CGMS), carbohydrates must be consumed immediately. If blood glucose is <4.0 mmol/l, a waiting period of at least 45 minutes is required before resuming driving (in case of doubt, a capillary blood glucose test is recommended).

At the beginning of a treatment with a higher risk of hypoglycaemia, fitness to drive is only considered valid once the aforementioned conditions are met and, in particular, it is ensured that hypoglycaemia can be reliably avoided while driving a motor vehicle.

In case of very high risk of hypoglycaemia (≥1 severe hypoglycaemia grade III per year and/or hypoglycaemia unawareness), a special assessment by a specialist in endocrinology/diabetology is required.

After an episode of severe hypoglycaemia (grade III) for holders of a driver's licence in the first medical group, ability to drive is only granted under the condition of wearing a continuous glucose monitoring system (CGMS) or performing 6–8 capillary blood glucose measurements daily *for at least one year*.

The measures required for each hypoglycaemia risk level when driving motor vehicles for drivers in the first medical group are summarised in table 3.

### Guidelines for driver's licence holders of the second medical group (D, D1, C, C1, professional passenger transport permit [BPT], traffic experts)

For the initial registration or renewal of a driver's licence in the second group, the following conditions must be met for individuals with diabetes mellitus:

- No traffic-relevant diabetes complications (diabetic eye disease impairing vision, nephropathy, neuropathy, no traffic-relevant macrovascular complications).
- No traffic-relevant restrictions in the cardiovascular system and no traffic-relevant impairment of kidney function with a significant impact on general health.
- *No significant hyperglycaemic derangement* (no issuance or renewal of the driving licence, if HbA1c >8.5%)

### Therapy with risk of hypoglycaemia

Fitness to drive may be granted under particularly favourable circumstances under the same conditions as in the first medical group. Specifically, the following applies:

#### Categories D and D1

According to minimum medical requirements, fitness to drive for categories D and D1 is excluded.

Suitability to drive for categories D and D1 can be assessed by a permission level 4 physician as an exception permit according to Article 7, Paragraph 3 of the Road Traffic Ordinance (VZV), provided the following conditions are met:

- Treatment and monitoring by a specialist in endocrinology and diabetology.

- Type 1 diabetes with hybrid closed-loop insulin pump therapy and continuous glucose monitoring, or
- Type 2 diabetes with ultra-long-acting basal insulin and the use of a continuous glucose monitoring system.
- No severe hypoglycaemia in the last twelve months.
- Hybrid closed-loop insulin pump therapy and continuous glucose monitoring (type 1 diabetes), or continuous glucose monitoring (type 2 diabetes) for at least three months.
- Preserved hypoglycaemia awareness (Clarke Score <4).
- Confirmation from the treating specialist in endocrinology and diabetology that the affected person has been trained and is proficient in the use of hybrid closed-loop insulin pump therapy and continuous glucose monitoring (for type 1 diabetes) or continuous glucose monitoring (for type 2 diabetes).

Categories C and C1, Permit for Professional Passenger Transport (BPT), Traffic Experts

For categories C and C1, for the permit for professional passenger transport, as well as for traffic experts, fitness to drive is granted under the following conditions:

- Stable glucose control with a therapy that does not result in hypoglycaemia (i.e. a therapy other than insulin, sulfonylureas/glinides).
- Stable ability to prevent hypoglycaemia and regular glucose monitoring at low, medium, high and very high hypoglycaemia risk (table 4).
- There must always be an assessment by a specialist in endocrinology/diabetology and an evaluation by a traffic specialist (physician with at least permission level 3).

Required intervals for issuing a certificate for road traffic authorities

The control interval for diabetes management is determined by the treating physician. The better the glycaemic control, the longer the control interval can be. The following general guidelines apply:

1. Newly diagnosed type 2 diabetes without insulin or sulfonylurea treatment: Check-ups with the doctor to determine HbA1c, assess self-monitoring of blood glucose or continuous glucose monitoring system every 3–4 months, annual measurement of eGFR and albuminuria, and peripheral neuropathy using a reflex hammer, vibration test at the base joint of the big toe (first metatarsal joint) and with a monofilament. Annual to every two year report from the ophthalmologist, including visual acuity, visual field and retinopathy grade. A certificate for the road traffic authority every 3 years is sufficient. With optimal conditions, this interval can be extended to 5 years.
2. Newly diagnosed type 1 diabetes mellitus: Motivation for the use of CGMS (continuous glucose monitoring system) and also the use of a hybrid closed-loop insulin pump. Check-ups as for newly diagnosed T2DM but with a diabetologist. First ophthalmologist’s report to be requested after 5 years then, depending on the ophthalmologist’s assessment, at least once every 1–2 years. The interval for the certificate to the road traffic authority is initially 1 year; with optimal conditions and no severe hypoglycaemia, every 3 years, and in the best case, every 5 years.
3. For longstanding type 1 or type 2 diabetes: Check-ups with the diabetologist (for type 1 diabetes) or with the general practitioner (for type 2 diabetes) every 3 to 4 months, along with monitoring of the parameters mentioned above. At least once a year, a report from the

Table 3:  
Risk of hypoglycaemia and required measures, first medical group (A, B, A1, B1, F and C1 for private use).

Category	Therapy	Action
No risk	Metformin, GLP-1 receptor agonists, GLP-1/GIP-receptor agonists, DPP-4 inhibitors, SGLT-2 inhibitors or their combination and no therapy with insulin, sulfonylureas or glinides	No blood glucose measurement necessary before or during the journey
Low risk	Ultralong-acting basal insulins (degludec/glargine U300) or gliclazide or glinides	No blood glucose measurement necessary before or during each trip Hypoglycaemia prophylaxis and blood glucose meter in the vehicle
Intermediate risk	Long-acting insulins (glargine 100, detemir) or Ry-zodegà once or twice daily or basal-bolus insulin therapy (including smart pens) with continuous glucose monitoring systems (CGMS) or hybrid closed-loop insulin pump systems (HCL)	Capillary blood glucose measurement before each trip Hypoglycaemia prophylaxis and blood glucose meter in the vehicle CGMS: No capillary blood sugar measurements, due to provision of predictive low glucose alerts If blood glucose <4.0 mmol/L, correct with rapid-acting carbohydrates and wait for 45 minutes
High risk	Basal-bolus insulin therapy without CGMS or non-hybrid closed-loop insulin pump systems or long-acting sulfonylureas (not gliclazide/glinide)	Capillary blood glucose measurement before driving and during longer trips Hypoglycaemia prophylaxis and blood glucose meter in the vehicle If capillary blood glucose 4–5 mmol/L, correct with 10–20 g carbohydrates No driving if capillary blood glucose <4.0 mmol/L If capillary blood glucose <4.0 mmol/L, correct with rapid-acting carbohydrates and wait for 45 minutes
Very high risk	≥1 severe hypoglycaemia/year and/ or hypoglycaemia unawareness (Clarke Score 4 or higher)	Assessment by a specialist in endocrinology/diabetology Ability to drive only with continuous blood glucose monitoring (CGMS) or 6–8 capillary blood glucose measurements daily Hypoglycaemia prophylaxis and blood glucose meter in the vehicle If blood glucose <5.0 mmol/L, correct with carbohydrates No driving if blood glucose <5.0 mmol/L If blood glucose <4.0 mmol/L, correct with rapid-acting carbohydrates and wait for 45 minutes

ophthalmologist is required. The interval for the certificate to the road traffic authority depends on the existing complications of diabetes, blood sugar control and severe hypoglycaemia: ideally every 5 years, otherwise every 3 years or annually if blood sugar control is insufficient.

4. Higher categories (second medical group, which excludes C1 for private use): Certificate interval is annually.

## Conclusions

In recent years, several pharmacological and technological innovations have revolutionised diabetes care. Continuous glucose monitoring system (CGMS) technology was developed in 1999, but it has only recently become increasingly integrated into diabetes therapy. Today, except for insulin, none of the treatments recommended for type 2 diabetes mellitus causes hypoglycaemia, and the risk of hypoglycaemia with ultra-long-acting insulins is lower. As a result, recommendations for driving motor vehicles have had to be adjusted [8]. Since hypoglycaemia is the greatest risk factor for impaired driving ability, the latest technology (CGMS coupled with hybrid closed-loop insulin pumps) is able to reduce the number of hypoglycaemic events and blood glucose fluctuations. In addition, HbA1c and time in target range can be improved. Patients with

type 1 diabetes mellitus are now, in exceptional cases, allowed to hold a licence in higher vehicle categories.

With the analysis of CGMS data, an objective assessment of the frequency of hypoglycaemia grade 1 and 2 is now possible (table 1), which was previously only partially possible with blood glucose logs (not all hypoglycaemia episodes were recorded, particularly nocturnal hypoglycaemia or were not entered in the glucose control logs).

The Federal Office of Public Health has thus far set the indications for reimbursement of continuous glucose monitoring systems rather high. However, as the prices of these systems have fallen or are expected to fall further, this working group believes that every patient with type 1 diabetes mellitus who accepts technology should have access to an hybrid closed-loop pump coupled with CGMS. Likewise, patients who are treated with insulin should also have the opportunity to use a CGMS. This also applies to gestational diabetes and diabetes during pregnancy. Since these systems warn of impending hypoglycaemia, they will also improve road safety, and the safety margin for blood glucose, which was previously set at 5 mmol/l, can be lowered to 4 mmol/l. With these new recommendations, all driver's licence holders are able to achieve the blood glucose control recommendations of the SSED, including pregnancy; for CGMS users, blood glucose measurements every 2 hours while driving are no longer necessary.

**Table 4:**

Hypoglycaemia risk and required measures, 2<sup>nd</sup> medical group (D, D1, C, C1, permit for professional passenger transport, traffic experts).

Category	Therapy	Action
No risk	Metformin, GLP-1 receptor agonists, GLP-1/GIP-receptor agonists, DPP-4 inhibitors, SGLT-2 inhibitors or their combination	No blood glucose measurement necessary before or during the trip
Low risk	Ultralong-acting basal insulins (degludec/glargine 300) or gliclazide or glinides	No suitability to drive for driving license categories D and D1; exception permit as mentioned above, traffic medical assessment by level 4 is mandatory
		Capillary self-monitoring of blood glucose levels 3–4 times daily (or CGMS)
		No blood glucose measurement necessary before or during each trip
		Hypoglycaemia prophylaxis and blood glucose meter in the vehicle
		Assessment by a specialist in endocrinology/diabetology and evaluation by a traffic specialist (physician with at least permission level 3)
Intermediate risk	Long-acting insulins (glargine 100, detemir) or Ry-zodeg® once or twice daily or basal-bolus insulin therapy (including smart pens) with continuous glucose monitoring systems (CGMS) or hybrid closed-loop insulin pump systems (HCL)	No suitability to drive for driving license categories D and D1; exception permit as mentioned above, traffic medical assessment by permission level 4 physician is mandatory
		Blood glucose measurement before each trip
		Hypoglycaemia prophylaxis and blood glucose meter in the vehicle
		CGMS: No capillary blood sugar measurements, since alarm function
		If capillary blood glucose <4.0 mmol/L, correct with rapid-acting carbohydrates and wait for 45 minutes
High risk	Basal-bolus insulin therapy without CGMS or non-hybrid closed-loop insulin pump systems or long-acting sulfonylurea (not gliclazide/glinide)	Assessment by a specialist in endocrinology/diabetology and evaluation by a traffic specialist (physician at least permission level 3)
		No suitability to drive for driving license categories D and D1
		Normally 3 months' waiting time
		Capillary blood glucose measurement before driving and during longer trips
		Hypoglycaemia prophylaxis and blood glucose meter in the vehicle
Very high risk	≥1 severe hypoglycaemia/year and/or hypoglycaemia unawareness (Clarke Score 4 or higher)	If capillary blood glucose 4–5 mmol/L, correct with 10–20 g carbohydrates
		No driving if capillary blood glucose <4 mmol/L
		Assessment by a specialist in endocrinology/diabetology and evaluation by a traffic specialist (physician at least permission level 3)
		No ability to drive for driving license categories D and D1
		Waiting time of normally 3 months without severe hypoglycaemia
		Use of a continuous glucose monitoring system (CGMS)
		Capillary blood glucose measurement before driving and during longer trips
		Hypoglycaemia prophylaxis and blood glucose meter in the vehicle
		No driving if capillary blood glucose <5 mmol/L
		Close monitoring and assessment by a specialist in endocrinology/diabetology and evaluation by a traffic specialist (permission level 4 physician)



If hypoglycaemia occurs during driving, the vehicle must immediately be pulled over to the side of the road, the hazard lights turned on, the car key removed and the driver must move to the passenger seat. The hypoglycaemia should be corrected with rapid-acting carbohydrates (emergency supply in the car). Since the brain takes longer to fully regain its responsiveness after prolonged hypoglycaemia, a waiting period of 45 minutes is required before continuing driving. With the use of technology, such situations should become significantly rarer (especially when CGMS is coupled with hybrid closed-loop insulin pumps).

### Potential competing interests

All authors have completed and submitted the International Committee of Medical Journal Editors form for disclosure of potential conflicts of interest. *RL* received fees for lectures, presentations, speaker's bureaus, manuscript writing or educational events from Abbott, Amgen, AstraZeneca, Boehringer Ingelheim, Bayer, CAP (Pharmacist working group), Daiichi Sankyo, Eli Lilly, Medtronic, Novo Nordisk, MSD, Roche and Sanofi, and support for attending meetings and/or travel from Novo Nordisk, all not related to this work. No other potential conflict of interest related to the content of this manuscript was disclosed.

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## Appendix

- a) Clarke-Score
- b) Medical certificate: Ability to drive and diabetes mellitus
- c) Information sheet: Drivers with diabetes mellitus

Clarke Score for verification of the hypoglycemia awareness (*adapted for Switzerland*)

1. Choose a statement that best describes you (only one answer)!

- ☐ „I always experience symptoms, when my blood sugar is low“  
☐ „I sometimes experience symptoms, when my blood sugar is low.“  
☐ „I never experience symptoms, when my blood sugar is low.“

2. When your blood sugar is low, do you experience less symptoms than you used to?

- ☐ no ☐ yes

3. How often, in the last six months, did you experience severe hypoglycemia, during which you felt confused and were not capable of correcting the hypoglycemia without losing consciousness?

- ☐ never ☐ 1 or 2x ☐ every other month ☐ monthly ☐ more than 1x/month

4. How many severe hypoglycemia episodes did you experience during the last year, during which you lost consciousness or had seizures or needed a glucagon or glucose injection?

- ☐ none ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6  
☐ 7 ☐ 8 ☐ 9 ☐ 10 ☐ 11 ☐ 12 or more

5. How often, during the last 4 weeks, did you experience blood sugar values < 3.9 mmol/l with symptoms?

- ☐ never ☐ 1-3x ☐ 1x per week ☐ 2-3x per week ☐ 4-5x per week ☐ almost daily

6. How often, during the last 4 weeks, did you experience blood sugar values < 3.9 mmol/l without symptoms?

- ☐ never ☐ 1-3x ☐ 1x per week ☐ 2-3x per week ☐ 4-5x per week ☐ almost daily

7. How low must your blood sugar be, in order to feel any symptoms?

- ☐ 3.3 – 3.8 mmol/l  
☐ 2.8 – 3.3 mmol/l  
☐ 2.2 – 2.7 mmol/l  
☐ below 2.2 mmol/l

8. How reliable are you at recognizing, based on your symptoms, that your blood sugar is low?

- ☐ never ☐ barely ☐ sometimes ☐ often ☐ always

**Assessment Clarke Score for verification of the hypoglycemia awareness:**

**Questions 1 – 4:** All answer apart from 1. answer = 1 point

**Questions 5 und 6:** If answer 5 < answer 6 = 1 point

**Question 7:** Answers 3 and 4 = 1 point

**Question 8:** First 3 answers = 1 point

(Maximum: 8 points)

0–2 points: Normal

4–8 points: Reduced awareness of hypoglycemia



## Medical certificate: Fitness to drive and diabetes mellitus

Name:

Birth date:

1. **Diagnosis:** Diabetes mellitus ☐ Type 1 ☐ Type 2 ☐ Specific Diabetes **since:**
2. **Diabetes Treatment:**  
☐ oral Therapy (or GLP1-RA, Dual-Agonist) ☐ Sulfonylurea/Glinide  
☐ Insulin treatment with: ☐ ultralong-acting basal insulin ☐ Basal insulin, co-formulated insulin ☐ Basal-Bolus  
☐ Insulin pump without CGMS ☐ Insulin pump with CGMS
3. **Diabetes-Überwachung:** ☐ continuous glucose monitoring (CGMS) ☐ capillary glucose measurement
4. **Hypoglycemia risk level for motor vehicle drivers according to guidelines SSED, SDS and SSLM**  
☐ no risk ☐ low risk ☐ medium risk ☐ high risk ☐ very high risk risk
5. **Instructions on preventing hypoglycemia while driving and compliance:**  
Instruction given (date): Patient Leaflet handed over (date):  
Level of knowledge/compliance: ☐ good ☐ sufficient ☐ insufficient
6. **Have there been severe hypoglycemias (grade III) in the last year?**  
☐ No ☐ yes (if yes: when and how often)?
7. **Laboratory values:**

Date	HbA1c	Other Lab values

8. **Are there traffic-relevant diabetes complications?** ☐ No ☐ yes  
(Retinopathy, Neuropathy, Chronic kidney disease, Peripheral arterial vascular disease)
9. **If yes, which one?**
10. **Vision:** The last ophthalmological check-up (report attached) took place on:
11. **Is the fitness to drive given from an endocrinological point of view?** ☐ No ☐ Yes  
If yes, for which category? ☐ Group 1 (including C1: Private use) ☐ Group 2
12. **The next examination with certificate is scheduled in:**  
☐ 1 year ☐ 2 years ☐ 3 years ☐ 5 years

**Comments or information about other diseases relevant to traffic medicine?**

The undersigned doctor confirms that he or she has written this certificate in knowledge of the "Guidelines for Driving Fitness and Driving Ability in Diabetes" of the SSED, SDGS and SSLM.

Place and date:

Signature and stamp:

**Reference form:** "Medical certificate: fitness to drive and diabetes mellitus". Approved by the SSLM and SSED.  
The form is used by the family doctor/diabetologist to answer the questions about fitness to drive, based on the "Guidelines regarding driving fitness and driving ability in diabetes mellitus" of the SSED and SSLM, published in 2025.

## Fact sheet: Drivers with diabetes mellitus<sup>1</sup>

Applies to persons with diabetes mellitus treated with medications with a **risk of hypoglycaemia**:

**Insulin, sulfonylurea** (Gliclazide®, Diamicon®) **or Glinide** (Novonorm®)

Fundamental	
Carry in the vehicle	<ul style="list-style-type: none"> <li>▪ <b>Fast resorbing carbohydrates</b> To be taken in case of imminent hypoglycemia: e.g. soft drinks, liquid energy concentrate, dextrose, etc.</li> <li>▪ <b>Food during driving</b> Travel time more than an hour: fruit, crispbread, dried fruit, bars, etc.</li> <li>▪ <b>Blood glucose meter and diabetes certificate</b></li> </ul>
Refraining from driving under the influence of alcohol	Alcohol worsens hypoglycemia perception, hypoglycemia is more likely
Respect meal times	
Before the start of the journey	
<p><b>Persons with diabetes <u>without</u> CGMS (continuous glucose monitoring system): blood glucose measurement before driving</b></p> <p><b>Blood sugar below 4 mmol/l: No driving</b></p> <ul style="list-style-type: none"> <li>▪ Intake of 20 g carbohydrates</li> <li>▪ Waiting time of 45 minutes</li> </ul> <p><b>Blood sugar 4-5 mmol/l:</b></p> <ul style="list-style-type: none"> <li>▪ Intake of 10-20g carbohydrates</li> </ul>	<p><b>Persons with diabetes <u>with</u> CGMS</b></p> <p><b>Blood sugar below 4 mmol/L: No driving</b></p> <ul style="list-style-type: none"> <li>▪ Intake of 20 g carbohydrates</li> <li>▪ Waiting time of 45 minutes</li> <li>▪ If in doubt, confirm blood glucose level by capillary glucose measurement</li> </ul>
<b>The blood sugar should NEVER be below 4 mmol/l!</b>	
<b>Precautionary measures after physical exertion:</b>	<p><b>If insulin dose is not reduced</b> and blood sugar between 4 and 5 mmol/l:</p> <ul style="list-style-type: none"> <li>▪ Mandatory increased intake of carbohydrates (10-20 g before the ride and 10 g per hour during the ride)</li> </ul> <p><b>If insulin dose is reduced</b> and blood sugar between 4 and 5 mmol/l:</p> <ul style="list-style-type: none"> <li>▪ Take 10 g carbohydrates</li> </ul>
<b>Precautionary measures after preceding meal:</b>	<p><b>Blood sugar between 4 and 5 mmol/l:</b></p> <ul style="list-style-type: none"> <li>▪ Take 10 g carbohydrates</li> </ul>
In the case of treatment with <b>ultra-long-acting insulins (Tresiba®/ Toujeo®/Xultophy®)</b> , once daily <b>gliclazide or glinide</b> and not in combination with other medications that cause hypoglycemia, blood glucose measurement before driving may be omitted.	<p><b>Quickly available carbohydrates and blood glucose meters</b> must be carried in the vehicle</p> <p>If there are any uncertainties regarding the treatment regimen and hypoglycemia risk level, the attending physician should be consulted.</p>
During the journey	
<p><b>At the first signs of hypoglycemia:</b></p> <p><b>Caution:</b> Hypoglycemia is generally less noticeable when driving</p>	<ul style="list-style-type: none"> <li>▪ <b>Stop immediately</b> (even if you are prohibited from stopping, switch on your hazard lights) and take 20 g of carbohydrates.</li> <li>▪ <b>If no CGMS: Capillary blood glucose measurement</b></li> <li>▪ <b>Continue the journey only after at least 45 minutes waiting</b></li> </ul>
<b>For longer journeys</b>	<p><b>If no CGMS: Stops every 2 hours, blood glucose measurement:</b></p> <ul style="list-style-type: none"> <li>▪ If blood sugar is 4 - 5 mmol/l: take 10-20 g of carbohydrates</li> <li>▪ If blood glucose &lt; 4 mmol/l: take 20 g of carbohydrates and wait 45 minutes</li> </ul>

<sup>1</sup>SGRM reference leaflet: "Drivers with diabetes mellitus". Approved by the SSLM and SSED.

The leaflet is based on the "Guidelines on Driving Fitness and Ability to Drive in Diabetes" of the SSED and SSLM, published in 2025.